

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

ANIMAL FEED SAFETY SYSTEM
PUBLIC MEETING

Tuesday, September 23, 2003

1:00 p.m.

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C O N T E N T S

	<u>PAGE</u>
Dr. George Graber, CVM, Moderator	3
Dr. Clifford Johnson, CVM, Comments	5
Dr. Stephen Sundlof, CVM, Opening Remarks	8
Tim Costigan, Prince Agri Products, Ingredient Manufacturer, Minerals	19
Dave Harlan, Excel, Ingredient Manufacturer, rendering Company	49
Joe Garber, Wenger Feeds, Feed Manufacturer	65
Mike Merkel, Doane Pet Care, Pet Food Company	85
Mike Davidson, California Department of Food and Agriculture - State Feed Safety Regulatory Program	104
Dr. Richard Wood, Food Animal Concerns Trust, Consumer Perspective	153

P R O C E E D I N G S

DR. GRABER: I think we're going to get started. My name is George Graber. I'm with the Center for Veterinary Medicine. We've got a full schedule today so we need to try to keep on time. I've got the first five minutes so off we go.

If you open up your packet to the agenda, I just want to go over a couple of quick items on here. The reception tonight is going to be out here near the bar from 6 to 8 p.m. instead of 6 to 7. Then tomorrow morning from 7 to 8 a.m. there will be a continental breakfast available outside the meeting rooms here and that's not written down on the agenda.

In your packet there are some bios for the speakers. We will not be going through any formal introduction of speakers so if you need to find out something about them just read the article from the podium. We also have a CVM Update, the Federal Register notice that announced the meeting, as well as a list of all the registrants as of probably 6:00 last night, so that's on the right-hand side of your packet.

On the left-hand side is some information about the break-out sessions that Gloria Dunnavan is going to talk about later this afternoon but each of you are assigned to a break-out session and that particular break-out session, you should have a list of the people who have been randomly selected to be in that group.

A couple of other items. There is a transcriber here. This is a government public meeting. We will be taking down what's said from the podium through today. Tomorrow, the break-out sessions, the transcriber will not be taking down those comments, but then tomorrow when we come back at 11:00 for reports of the break-out sessions the transcriber will be here.

If anyone has a wireless apparatus please put it on remote. Otherwise that little person--you know you go to those movies and you see that person being jack-knifed out of their seat? We've got somebody who's going to fill those shoes.

One other thing. Sometime today there will be an announcement that's going to be put up on the back of the room at the table to my left in the back here. It's an announcement of a one-day meeting being sponsored by

the CDC, Centers for Disease Control and Prevention, to be held sometime in January in Atlanta and it's going to be on bacterial contamination of animal feed and food-borne illness, so there will be some brochures on that today.

Okay, the first speaker coming up here for the next five minutes will be Clifford Johnson. Dr. Johnson is my boss. He's the director of the center, director of the Office of Surveillance and Compliance.

DR. JOHNSON: Thanks, George. George has given me five minutes but he's told me what to say, also.

It's certainly a pleasure to be here. We've been looking forward to this day, the team that originally worked this issue as it formed as a concept within CVM, and we decided to explore this opportunity in light of food security and some of the other things that are occurring today. So this concept was explored by a wonderful team of people that we have within CVM and I'll give you their names in a few seconds. So here we are today now to get comments on the concept as we envision it.

I guess the participants are up there and you see we have a cross-section of industry here, people from various walks of life within the industry. We have participants from the federal government, states, academia, foreign governments, consumers and press, so we've got a really great group of people here today and some good speakers to give the kind of information that we're seeking.

The animal feed safety team was composed of a number of people, some from CVM, some from the Office of Regulatory Affairs, some from the Office of Counsel, so we've had a lot of people that have come together and all the people that are on this team or that gave input to this team are necessarily listed here because our team members, in turn, talked to people on the phone, by letter, and so forth, so there are many, many others who have contributed to this concept that they've put together for the animal feed safety team. We thought we would just list the primary members that met on a regular basis. I met with them from time to time and I was just amazed by the enthusiasm that they brought to this team and how sincere they were about this whole thing. So it

really turned out to be a great effort and we hope that what we learn here today will contribute to making that even better.

Let me just mention something about our speakers today since George has said we're not going to necessarily formally introduce them all. Our speakers are Dennis Byrne from the Herr Angus Farm, who will cover quality control procedures used on the farm; Tim Costigan, Prince Agri Products, who will describe the steps used by his firm to ensure safe mineral products. Mike Davidson, a feed control official with the California Department of Food and Agriculture, will describe what his state is doing with their feed safety program. Joe Garber, no relationship to George, I'm told, Wenger Feed, will describe the quality assurance program at his feedmill. Dave Harlan of Excel, who represents a rendering company and has started a HACCP program. Mike Merkel, Doane Pet Care, who will give us insight about the procedures used by his company, and also Dr. Richard Wood of the Food Animal Concerns Trust to present a consumer perspective. So we've got a good

group of speakers here and I look forward, as I'm sure many of you do, to hearing what they all have to say.

First we have to listen to my boss that I'm proud to introduce, the director of the Center for Veterinary Medicine, Dr. Stephen Sundlof.

DR. SUNDLOF: Thank you, Cliff. I want to welcome everybody. It's great to see the room is absolutely filled, standing room only. That's great. It just shows what an important issue this is and how wide an impact it has on this community.

First of all, let me just say that I have enjoyed thoroughly working with this industry, with the feeds industry, and that includes the renderers and the mineral supplements and everybody else. It's just been a real pleasure for me over the years that I've been in this position and that's why I look forward to seeing everybody here today. We really want to bring everyone in at the very beginning to capture all the good ideas that are out there and make sure that we hear all of the issues that people have.

So today we're going to be talking about the Animal Feed Safety System and I don't know how to

pronounce the acronym so I'll pronounce it some way and you can change it later. But the whole purpose of this is to develop a more comprehensive system for the whole feed cycle from--actually, not on the farm but from the time it becomes a component of feed all the way up to the point where it's fed and to have a system in place that will be a preventive system in nature, that will be risk-based, and that will be flexible enough such that there's a lot of room for--as long as we try and achieve the same goal, how we get to that goal can be very flexible.

We certainly at CVM appreciate the time that people have taken to come here. It is a busy time of the year now that we're into the fall again and again we do welcome that. We want to welcome all of the comments and we have some break-out sessions later this afternoon and tomorrow that we really want to get people's input, so I want to personally encourage you to provide as much input to us as possible. It won't stop with this meeting. There will be many other opportunities to provide additional input on this endeavor but we do want to begin collecting some of the ideas about what this Animal Feed Safety System should look like.

Well, how did we get started on this initiative? I've been in this job now nearly 10 years and when I came into it I had no idea of all the various issues surrounding animal feeds and it's really been fascinating for me just to be here at this time when all these different issues are presented. And I want to say that the U.S. feed system has really been remarkable when you compare it to some of the other countries' feed systems and the problem that they have as a result of that.

Well, feed safety is important to all of us in this room. We've all heard about a lot of the issues, BSE being obviously the most prominent in recent times, but other things such as PCBs and dioxin continue to come up now and then and dioxin is currently a hot topic. Salmonella issues that we've been dealing with for many years. Micotoxins, which have also been with us for a long period of time, but there's always new issues that are coming up, as we found out last year in Europe when they found hormones that came from a pharmaceutical firm in animal feeds. It was unintentionally introduced into animal feeds.

So there's always going to be different issues that will come up and we'll have to deal with those as the regulators of feed safety. Currently we've tended to deal with these issues one issue at a time, so we deal with the dioxin issue or we deal with the BSE issue or we deal with the Salmonella issue without really taking the broader look at do we have a good overall system in place that is not as sensitive to the individual problems but would have more preventive effect on any problems, either anticipated or unanticipated, in animal feed that might come up.

Our current system tends to focus on end product sampling rather than putting in place a preventive program, so we want to talk about how a preventive program might look. And we're very encouraged by a lot of the efforts that have already taken place within the various industries. You know, the feed manufacturers are putting in place various feed safety programs that are on a voluntary basis right now and again we want to take the best parts of those efforts and try and combine those into our final Animal Feed Safety System.

This program that we're going to be talking about in the next couple of days also fits in very well with the Commissioner of the FDA's strategic plan, which he announced on August 20. One of Dr. McClellan's highest priorities, one of the five goal areas under the strategic plan, calls for FDA to provide high-quality, cost-effective oversight of industry manufacturing processing and distribution in order to reduce risk and that pretty much captures the intent of having a comprehensive Animal Feed Safety System.

Another goal within the strategic plan is to assure the safety of the U.S. Food and cosmetic supply to protect consumers at the least cost for the public. So again the food safety mission of the FDA certainly comes through with our feed safety initiative.

Again I'm very proud to be part of a system that has had such a historically good record of safety. We've had little problems that come up here and there over the years, some anticipated, some unanticipated, most of them unanticipated, but clearly when you look at other countries and especially when you look at Europe and the problems that they've encountered as the direct result of

their feed safety systems, it gives me a great sense of pride again to be part of the U.S. system and that's due almost entirely to everybody in this room.

But now we have a new threat and the new threat is bioterrorism and our efforts to mount a counterterrorism effort as it applies to animal feeds and I think this is going to be an area that is going to receive a lot more attention in the future. That is actually looking at agricultural bioterrorism on a national basis, getting the agencies who are responsible for food safety and animal safety together with Homeland Security to develop a comprehensive system to mitigate against agricultural terrorism and feed safety is going to have to be an integral part of that, so this is the right time to be having these conversations.

And because the U.S. must maintain its world leadership in feed safety because the food markets are international now, we also have to look across the borders to our trading partners and because we are a net exporter of feed components, make sure that our system will be sufficiently robust to satisfy the needs of our

trading partners. We'd like to see the U.S. continue to be the world leader in feed safety.

So the Animal Feed Safety System could be considered as a logical and appropriate mechanism for all of these goals that I've just talked about but what about the time lines? We've decided that we want to make sure that there's sufficient time to put in place the best system that we can. On the other hand, we don't want to sit around waiting and we want to make sure that this initiative has a lot of emphasis behind it. So we've projected that we want to be completed with this task by 2006. That may seem like a long time but with a system as complicated as the animal feed system, there are going to be lots of issues that we're going to need to study and have in place and make sure that we get a lot of input from a lot of different people in order to make it the best program it can possibly be.

We'll need to keep a steady pace. In about three years, which would be 2006, we will have to complete a significant amount of work, including developing the whole concept of the Animal Feed Safety System, developing our regulatory approach, and if

needed, proposing regulations. Hopefully we won't have to propose any new regulations but if there are certain areas that we just don't have the authority to regulate now and we think as a group that this is important, then regulations may be necessary and we would try and have those out for comment by 2007.

We want our Animal Feed Safety System to be a risk-based system. I think everybody agrees with that. Any plan that FDA endorses will certainly have to be risk-based. Our regulatory attention must focus on areas that offer the most significant animal health and public health impact and are of the greatest risk. The plan will also be designed to deal with the risks we know and again the risks that we don't know. And it needs to be comprehensive. That means it needs to not only include feed mills but everybody in the chain. So the suppliers and manufacturers of supplements for animal feeds, the transportation that hauls feeds, everybody in that chain needs to be under the plan.

It must minimize the risk to animals themselves from physical, chemical and biological hazards and it

also must minimize the risk to humans from the same types of hazards.

The components of the plan will be, like other plans that we have, it will obviously involve some form of recordkeeping and it will involve some development of standard operating procedures but, at the same time, we want the system to be very flexible. We want to have established goals but a lot of flexibility in achieving those goals.

The feed industry has developed already, as I mentioned earlier, a number of innovative programs and as these programs have shown to be effective and in line with the goals of the Animal Feed Safety System, we'll consider making them part of the AFSS plan. AFCCO we know, because we're participating with AFCCO, we will also consider AFCCO's process control program for the feed industry. Whatever system we develop will rely heavily on our state counterparts to make this program work, so we're very happy and enjoy working with the states and with AFCCO and we'll consider their process control program in developing the Animal Feed Safety System.

Again I want to thank the speakers and I don't need to introduce them now because Cliff Johnson just did, so you know who everybody is here. After the speakers this afternoon--so the speakers will all present and then we'll ask for comment and we'll be dividing up into break-up groups, break-out groups, to answer some questions, specific questions that have been developed by CVM's AFSS team. The questions are designed to help provide us with information and advice about what an Animal Feed Safety System should look like. And Glo Dunnavan will give you more information about that later on today.

Keep in mind that the feedback that you provide is absolutely critical to making this system work. We will probably have numerous other opportunities to meet but even in the absence of meetings, your comments are always welcome. We want to hear from you. We'll try and keep everybody up to date and present on our website, so I encourage all folks to check in on occasion with our website.

And with that, I wish you a very productive meeting and thank you all very much again.

[Applause.]

DR. GRABER: Right on time. Very good.

Next on the program is Tim Costigan. He's the manager of quality and analytical services for Prince Agri. Tim?

MR. COSTIGAN: I think the easy part is probably giving a presentation this afternoon. The hard part is probably going to take place in the break-out sessions. One of the difficulties that all the speakers are going to be presented with today is taking something that they could probably talk about for about two weeks and condensing that to 20 minutes. So if we go a little bit fast, kind of bear with us.

One of the things we were asked to do is explain a little bit about our companies. Prince Agri Products, along with a number of other manufacturers, produce trace mineral premixes for the animal feed industry and they also supply straight ingredients. So our company takes various mineral products and sells those as straights, like copper sulphate calcium carbonate, calcium phosphate, those types of minerals. Also specialty products--some of the flavoring or the palletants, as

they're called, a number of other products that go into the animal feed industry. They then take those products, blend those together, and make trace mineral premixes.

Now at Prince we maintain over 3,000 different trace mineral premix formulations, which are all custom designed by our customers. The way we put those together is really indicated by the slide. What we have is ingredients that we bring in in bulk. We'll bring in full truckloads of those products, put those in bulk tanks, and then those are metered onto a load cell.

Secondly, we may add those from minibins. We'll bring in super-sacks of product, put those into these smaller bins, minor quantities of those may be added. We have bag break. In some cases you're adding 150 pounds, 175 pounds. You actually take that from bagged product, 50-pound bags of product. Then down right over the mixer is what we call a hand delivery system where we're taking the micro ingredients--these are the ingredients that are added as less than 50 pounds--and those are put directly into the mixer in order to make sure that those do, in fact, get into that mix, that they're not lost in transition.

The load cells are hooked to a computer system. The computer system then controls the addition of each of those ingredients and records that. Along with that, we also do--and I'll get into that in a little more detail--we also do some checking of those numbers as they go through and process a batch. That material is then blended in a mixing system and then transported up to a packing tank. From the packing tank it can be put into bulk truck again, into super-sacks or into 50-pound bags. So that's kind of an overview of the premix system.

Some of the other things that we're somewhat concerned about is controlled formulations. When a customer sends a formulation to our headquarters we then put that into our systems. What we send down to the plants are the actual working copies of that and the mix regards are controlled documents so that we know that those are up to date, they're current, and when any changes are made those are replaced.

The computer-controlled ingredient addition helps us in ensuring that we do get the proper quantity in there but there is a secondary check of each of those numbers as they go through and they do mark the mix

record manually to ensure that the read-out on the scale does come to the desired quantity.

Then there are electronic scale records that help us trace back to each batch. So there's really a three-check system. One of the things that we try to incorporate into our systems is that each important aspect is checked at least three times, three independent checks or three ways of checking the same thing. That redundancy gives you a lot better assurance that the product is going to be as desired.

One of the main ingredients, and I think you'll see this through any of the risk assessment programs, is that you have to take the risk on early in the process. You can't inspect the quality into the product at the end of that. So one of the main problems that we have and one of the main issues that we have to address is our incoming raw materials. Same with the feedmill, same with the companies who are delivering that feed to their animals.

So in our case the raw materials and the specifications are based upon a number of things. Number one is the process. We buy products from mining

processes, we buy them from chemical processes, et cetera. We have to understand the process in order to know the weak points in that process. When you understand the weak points in the process you know what to check on an on-going basis to assure that the material is up to quality, is up to snuff.

The second thing you have to really look at is the end use. Our company provides minerals to the animal feed industry. Our sister company provides them to a lot of other industries. So in looking at the final use of the product, you decide what's the most important to be checked upon, what's important to the customer, what affects this product? The specification has to be related to both of those things. You have to write a specification that ensures that your supplier hasn't changed something or something has moved in his process. You also have to be sure that it's proper for your customer's use and knowing the hazards for your customer becomes key.

Inbound ingredients are sampled and retained in our plants for one year, so if there is an issue that comes up we can go back and pull actual samples from each

shipment that's brought in. We have scheduled chemical and physical analysis. You don't need to do the same analytical work on every product that's brought into the plant. A load of calcium carbonate that's used as a diluent certainly has less effect upon the quality of that finished product and the use than a load of zinc oxide, which may contain heavy metals or other things of that nature.

So sampling is done on inbound materials again based on experience but by lot, by shipment, and by month, as well, so that testing is done, that data is reviewed from a QC function, and then the product released or in some cases actually used prior to release there.

Complete analysis is done annually. That's one of the things that we try to do. You try to address all the known issues. You try to learn about issues that you weren't previously aware of. So a complete analysis for us gets quite lengthy and I'll explain that in a little bit. Actually, the next slide will go into some of that.

To give you an example, one of the products that we purchase is zinc oxide. Now in order to understand

exactly how to approach that zinc oxide that we produce, it's primarily made by the Wales kiln process. In the Wales kiln process you take a zinc-bearing ore, you heat that up to a fairly high temperature. You actually cook off the zinc. You're volatilizing the zinc to a zinc fume. That zinc fume is then captured, oxidized, and you create zinc oxide. Unfortunately, there's some byproduct to that. There's also some lead and some arsenic that come over with that zinc. Now the lead and the arsenic is certainly detrimental to animal feed so you want to make sure that that's removed.

The second part of that process is to heat that product up again to a lower temperature where only the zinc is volatilized, so one of the checks that we have in place on inbound product is to make sure that the zinc concentration is correct because that's what our customer formulates to. That's what he's after. We want to make sure that he gets what he's after.

But secondly, you have to take a look at the process and the known hazards and in this case lead, cadmium and arsenic are three elements that we analyze on the inbound product and monitor on a close basis because

we know that a failure in his process could result in product that's detrimental.

In the case of annual reviews, we talk about known hazards. You also have to look for things you don't know to be present. One of the things we do is the analysis of the ones listed above, of course, but annually we'll pull a sample, have that tested for dioxin. That's one of the more recent known hazards.

We also do a scan for 70 trace elements. Now a scan for 70 trace elements, it's a semi-quantitative scan and it gives you numbers that you then can compare to the previous year's results just to make sure that the process isn't drifting, some new or introduced or some other contaminant present that you hadn't expected.

Going back to the production process, it's kind of difficult when you're producing trace mineral premixes, especially custom trace mineral premixes, when you produce three tons of this one, five tons of that one, seven tons of that one, and then it takes three to five days in some cases to get all the analytical work back. So we have to put in real-time QC checks. Part of that real-time QC check is to pull a sample of the

product you're producing, every fifth back through there, and you lay that on a piece of paper and then compare that to the actual what we call a standard from a previous run. What you're looking at is not just the color. You're looking for the various ingredients that are present. You can easily pick out magnesium oxide, copper sulphate, ferrous sulphate. A lot of the ingredients of various oxides you can see in that batch.

So an appearance check is something that the operator can look at as he's bagging the product to assure that there's consistency within a batch and then from batch to batch.

We look at batch yields. If you formulate to 2,000 pounds, you expect to get 2,000 pounds. It seems pretty common sense. But if there's a problem with a contamination or flush left within the system, that's where you're going to catch it.

The next thing that we look at is periodic analysis. For periodic analysis we have various reasons to analyze samples. I'll go through those a little bit later but we are analyzing batches periodically, we do use that data to evaluate both the process, the raw

materials, and to report data to customers, as required by them.

The magnet inspection. If we look at other concerns that we have within our system, magnet inspection is one of those. One of the foreign materials that we're worried about is scrap metal coming in or if we have a break in a piece of production equipment, some of that metal getting through the system. So a magnet inspection just to remove the contaminants is one thing but we also document that so we can understand what contamination is taking place and if there's more today than there was previously and if we need to go back and look at some of the raw materials.

The inventory reconciliation is used if we come up with a problem putting a batch together, we have a yield that's not expected, and we need to try and investigate what happened there. We can go back and check our raw material inventories to see if those are all in line, as well as doing the analytical work on that.

One of the things that you're asked to do is keep a lot of records. If you're going to go back and

investigate a situation you need good records in order to complete that investigation. It's one thing to have an incident within a plant; it's another thing to take corrective and preventative action to make sure that those things don't continue to occur.

So some of the records that we put in place, we have custom formulations. As I said, there's over 3,000 of those. The tags and the preprinted bags are controlled by our formulations department. Only the current copy is issued to the actual plants producing the products. Any historical copies are kept in the office and away from the production facilities so that we know that only the current documentation or the current packaging is being used.

We have mix records on every batch that we put together. The mix record tells the plant what to put into each batch and then they use that to confirm that those additions were made. Scale records, electronic scale records are attached to those mix records to verify the weights and to give us a way to trace back to exactly what was ordered, what was added to the mixer, and in what sequence.

The receiving records, when we talk about shipping and receiving, the receiving records, any product coming in is sampled, records are filled out as to what lot numbers are received, et cetera. Same with shipping records. We have records of material going out and the load sheets reflect lot numbers and then the weights of each of those products that are shipped. So when you're talking about traceability, we try to help our customers by recording lot numbers that we ship to them. If there is a recall, at least we have some way to help them trace that back.

Sales records are present there if we want to go back and look at when a product was shipped, what carrier moved that material, et cetera. All that information is available.

Analytical records are available for any of the products that we analyze and within our laboratory we're running over probably 50,000 mineral assays a year. All that information is available and can be traced, again back by item number and lot number.

Then audit records. We do audits out in the plant. We do QC audits in the plant. There's a whole

list of audits that I'll go through but those records are maintained and used for reference.

If we look at traceability, it's one of the issues that especially for feed safety becomes a concern. When you run into a hazard, number one, you can inform your customers. If you discover that hazard and that product has been used, you have to have a way to know who to contact and who's been involved in that. Secondly, if the problem is discovered downstream, you need a way to trace that back through your system. So traceability becomes fairly important.

On ingredients, resale ingredients--we'll break those down a little bit. On resale ingredients, we actually track by the supplier's lot number. So if we bring a product in, a pallet of 50-pound bags, and we ship that out, we record that supplier lot number.

On consumed macro and trace ingredients, we actually track those by shipment. When a shipment comes in we don't record every single lot number within that shipment. We do, however, sample across that group and apply our own lot number to that material.

For consumed microingredients, we're actually tracking that by the supplier's lot number. So I talked about the ones that we dump directly in the mixer--those are used less than 50 pounds at a time--we have the lot number of each one of those and the reason is that one lot number of that may be used over several days of production or several weeks of production. So the volume involved in a recall would be quite large, so we do specify the lot number on each of those.

On that last point, the final product on our finished product, we do apply lot numbers to all of those. The lot numbers tell us what plant or location manufactured that, the actual day of the year, the year, and then the batch or the ton produced that day.

On traceability, on biosecurity, number of steps that we put in place. This has been since the 9/11 incident that we felt were helpful in containing some of the biosecurity issues. One is that visitors that are on premises must sign in and sign out and a visitor tag is issued. It's a way for us to more easily identify the visitors in the plants. Most of our plants are fairly small, everyone knows all the other employees, so when

they see someone that doesn't belong, it certainly gives them an idea of how to react or what to do.

The second thing is that any visitors that are on the premises must be accompanied by a Prince person so we're able to keep track of them, make sure what their activities are.

Employees, we check background before hiring now. We do a little more thorough job of that. Also training of employees on procedures, which is key. It's nice to put procedures in place but when it comes to the biosecurity, unless they thoroughly understand what their position is, how they're supposed to act and what they're supposed to do when circumstances arise, it really does not help you very much.

Materials. In order to control both inbound and outbound materials, we've started sealing all of our loads so everything inbound and outbound has a seal on it. The customers know what the seal is. They're numbered by our paperwork that accompanies it and the only thing that's left really not covered in that situation are LTL shipments, less than truckload

shipments. In that case the truck is opened and accessed a number of times en route.

Inspection of trailers and then review of paperwork becomes a little bit of a necessity there. A lot of the companies that we deal with we're buying product on pretty much a continuous basis. There's trucks that are scheduled in and we have agreements with the truckers on what products they should or should not be transferring in that equipment.

Contamination concerns for us really encompass the three levels, which most of you will--chemical, microbial and biological and physical. For us, the chemical is the big one. Toxic elements, such as lead cadmium, arsenic, mercury, can be present in some of these ingredients. By understanding how your suppliers produce the product and what the liability is there, you can certainly keep a handle on that.

Cross-contamination or incomplete blending become an issue. Some of the elements that we add to a trace mineral premix, for instance, the selenium is very toxic. It's needed in very small amounts but you can put a thimbleful into a premix and that's all you're adding.

So by keeping track of those and keeping track of any issues related to cross-contamination or incomplete mixing become another concern of ours.

There are a few concerns with organic materials. In this case pesticides and lubricants can be of concern and those are really the only things coming into our system of a biological nature. The nice thing about handling most of the minerals is that the microbial and aflatoxin, that type of stuff, are not a concern. Those kinds of things do not grow very well in most of the products that we handle.

Physical contaminants can be primarily explained or primarily represented by metal and glass. In the case of metal we actually have magnets through the production system to pull any of that material out. In the case of glass, we limit the exposure of glass in the facilities by covering any light fixtures, et cetera. We also do not allow people to take glass containers out into the plant. So we're minimizing the risk of contamination by keeping that material separated from the production areas.

So far as controlled documents, one of the other things that you have to do is if you're going to perform consistently day to day you have to have documentation that's out there, that's understood, and that's used. In our case part of our company is registered to the ISO standard. Prince Agri Products is not but they borrow a lot of things from that. I think one of the things you'll hear from a number of companies is that there's not one system that's complete, that has all of the aspects you need, but there are a lot of systems that have good pieces and we borrow from those.

In the case of document control, a lot of our procedures are set up in an ISO format. We have document and data control, three procedures. Purchasing, we have five procedures. Product identification and traceability, two procedures. Process control, 18. Inspection and testing, 17. Control of inspections, measuring and test equipment, five. Inspection of test status, three. Control of nonconforming product, one. Corrective and preventative action, two. Handling, storage, packaging, preservation, delivery, three. Control of quality records, one, and training, one.

What's important is that you take a look at the things that you expect people to do day to day, you document those and that they fully understand how to react to those.

Looking at audits, one of the things that we found and I think most of you people will find when you look at your production systems, et cetera, is that the best way to make sure that the procedures are followed and that things are happening the way you expect is to have someone review them frequently. To go out and do a yearly or a quarterly QC audit does not have the effect of an every-day audit. The same with regulatory. To go out once a year and do a regulatory audit is a good thing to do but you don't know what they're doing in between that unless there are some records or some verification of that.

What we do is monthly safety audits and that's a cross-functional group that does walk-throughs of the plant. They go out and they look for various hazards. They review some of the legislation that's coming up. They're more or less conscious of what the safety aspects are within the plant. We're speaking here more along the

lines of the OSHA safety rules but also anything that would affect the safety with the manufacturing process and contamination there.

Weekly sanitation audits to make sure that areas are kept clean, that clutter is kept to a minimum, that things are put away, that the process system is in order.

Periodic procedural audits. We have a number of procedures listed there. You do need to go back and review those and make sure that those are being followed correctly and that there is supporting documentation and that there's independent evidence out within the facility that things are being done. In other words, to give you one example, sampling of inbound materials. How do you know that samples are done? You look for the samples in the sample retention area. Also go out into the warehouse, take a look at the packages. If you don't find packages that have been opened and sampled, then chances are this is not being done. So that objective evidence is a good part of that audit.

The quality unit does a couple of areas that we really focus on. One of them is the annual comprehensive audit, and that encompasses all of the areas that we're

interested in kind of reviewing. It takes a look at the sanitation within the plant. It takes a look at process systems. It takes a look at statistical studies that were done. We take a look at the performance and the recording documentation of procedures that are followed. We take a look at safety records. We take a look at management policies, et cetera. So that whole thing is reviewed once a year.

The comparison of one year to the next, there is a point system associated with that, but it shows the plant which area they're strong in, which areas they're weak in.

Now one of the things that's really been helpful for us is to share that across the number of production facilities. By doing that, you find one area that's maybe suffering on one facility; another facility is very strong in that. They're able to talk to them and then develop procedures and put those into place, which are much more effective or really address the products more efficiently.

And the annual formulations audit. For us it's very key to be taking care of our customers' needs and

our customers' needs are for custom formulations. Everybody has their formula put together so they get maximum performance out of their system. The formulations audit, we actually send the formulations team from our corporate headquarters to each of the locations. They go through every single file that's there to make sure that the revision they're using is the current revision and is up to date.

Some of the statistical techniques that we have in place is we do a yearly mix plant error assessment. For us, these are key to improvement. The things that we're looking at is the amount of raw material variation in the product coming in the door. We take a look at the variation associated with the material introduction into the system. We take a look at mixing and segregation error and sampling an analytical error.

So if we take our final product going out the door and you measure those things, those are all the major portions of the error that's associated with that finished product. In the case of doing these evaluations, you can then focus efforts and product improvement efforts upon those individually. In some

cases the raw material variation may be the highest. In other cases you may have a production system that is not ideally suited to introduce zinc oxide, which may not flow quite as well as ferrous sulphate into a system. You can make improvements to that production system. You can make improvements to your raw material supply, et cetera, in order to limit that amount of variation.

Mixing and segregation is important to monitor in our business. We're in the business of putting together homogeneous mixtures. Now if we analyze just samples out of the mixer, we're kind of taking a short picture of that. You really want to analyze the product in the finished package that the customer's receiving. So we're doing a mixing system evaluation. We sample that finished product, we measure that variation. That variation is due to all three of those things--raw material variation, ingredient addition error, and then also mixing and segregation.

And when you're taking a look at the whole system, analytical error does play a part. It's nice to know that you have excessive variation in one component or another but if you're going to truly address that, you

need to know whether it's an analytical issue or not, so that certainly becomes a focus, as well as our error assessments.

Semi-annual mixing studies are performed or whenever we make major changes to a mixing system, perhaps replacing paddles or if we have a new portion of the system put in place or maintenance done on that.

And quarterly bag weight studies. One of the other aspects we've identified is a lot of our customers take a 50-pound bag and dump that into a batch of feed, so they're relying on us to put 50 pounds into that bag and we do statistical studies to assure that our packaging equipment is working effectively and that they are within the range that's expected.

Analytical work. We have a number of ingredients that we're bringing in. We really focus on those ingredients. We have scheduled sample submission at the plants based upon a number of things. One is supplier history and the amount of data. If you work closely with a supplier, a number of our suppliers we've worked with for in excess of 30 years. When you work with a company that long, they understand your needs, you

understand their needs. When you exchange data you become much more familiar with each other and you can relax some of those requirements.

Ingredient variation and previous concerns. If you have problems with a particular source or a particular supplier or if there's been a new hazard that has been identified, then you need to address those and the way that you address those is you increase the testing on those particular products.

Then the last thing is a complete yearly analysis, which we already spoke about.

Premixes, we test on samples. Whether safety or quality concerns, we may be testing every single batch. Selenium premixes are one of those cases. In the case of selenium, it's a very toxic substance. We bring in a product that's 45,000 parts per million. We then blend that down to something in the 1,000 to 10,000 parts per million range. We then blend that down another time into the lower part per million ranges, which go out to the feed companies.

So for us, to do that tiered blending is a very important QC effort in order to make sure that we do get

good distribution and that there are no issues with toxicity. Any of those concentrated mixes are analyzed per batch, so we do have a very good idea of what's going on with those and keep track of those.

Single batches are analyzed each day. One of the aspects that we have is if you know your raw materials are good, you're watching your raw materials, you know that your process is functioning correctly, the finished product should be good, so our efforts are then placed on monitoring that. Now if I do a mixer study once a year, I know that on that day it worked. Well, how do I know that it works every other day in between? So the idea of taking a single production batch and analyzing that, not only for tag guarantees but for all the other elements that are present.

In our case we have 17 elements that we monitor. Those 17 elements incorporate all of the raw materials that we bring into our plants. So we may not notice that there was a little bit of di-cal contamination in a load of limestone through just the analysis on calcium. However, when you see a peak on phosphorus where it's not expected, then you know that perhaps something's going on

and you need to go out and take a look. If it's a raw material addition, maybe it's a malfunction in the mixing system, those types of issues.

The last thing I have is any type of production issues. When you do come up with a yield that's incorrect, then you do want to go back and investigate that and we do the analysis on those.

The last thing I want to talk about is overall quality program. You want to apply the portions of existing programs that really fit your needs. In our case, biological is one of the lower level concerns because there's just not a lot of exposure. There's not a lot of things that can happen to the trace minerals. They're not friendly to the growth of microbials, et cetera.

So in our case we borrow from a number of different areas; HACCP is one. The risk assessment with HACCP is very good. In ISO, the control of documented procedures and just the overall control of documentation and training become very good.

With GMPs, hygiene, traceability, contaminations, those issues certainly need to be addressed and GMPs help you do that.

The focus needs to be preventative measures. In our case ingredient quality is certainly kind of up-front on the list of issues. Process evaluations is very high on there. You need to make sure that things are performing correctly in the process.

Then you want to do confirmatory testing. Confirmatory testing assures that the entire process is working correctly and that things haven't gone awry.

That pretty much wraps it up. Thank you for your time.

[Applause.]

DR. GRABER: Thank you, Tim.

Next on the program is Dave Harlan. He's the by-products manager, marketing manager for Taylor Beef, Cargill Meat Solutions.

MR. HARLAN: Good afternoon, everyone. I'm going to talk about more of the rendering role, where rendering fits into the bigger picture of food animal production. You can see rendered co-products used, raw

materials from the meat processing industry and from on farms and produce animal feed ingredients that are used for the manufacture of animal feed that is fed on the farm and also in pet foods. So it plays a very critical role in this whole entire cycle.

Typical fed cattle plant. These are the large plants that process young cattle, mostly out West. You see the red side is the processing of these animals into edible beef products. These facilities tend to have what's called an edible rendering process, which is the taking of fat and bones and producing edible tallow and bone for gelatin purposes.

Off of the dressing floor there's a by-product called offal, which goes to inedible rendering for the production of beefmeal and beef tallow, and we also raw blood that is processed into bloodmeal.

At Taylor Packing we don't have the edible rendering portion of it so our approach is a little bit different. Our dressing floor offal and fat, bone and fat, are transported over to our rendering facility, get mixed together and then ground in a raw state. They then enter a continuous cooking process at one end, move

through that process where the moisture is evaporated and come out the other end and hit a screen that basically splits that slurry into a liquid and solid fraction. The solid fraction ends up becoming the beefmeal. This solid goes to pressers which squeeze any residual fat out. You can see the bottom line. That fat goes over to the liquid side. The beefmeal is then in our process cooled, ground and screened, put into storage, and then eventually goes to our load-out and protein blending plants.

The liquids coming off the screen go over to a centrifuge, which takes some impurities out, some solid participate matter out of the tallow. That tallow then goes to a tank. In our process we filter it and any solids here go back to the right-hand side of the screen into the meat and bonemeal.

In trying to develop a comprehensive animal feed program at Taylor Packing we want to use many tools. These are some of the tools in our toolbox. It starts out with philosophy and commitment of the owners and the workers. We look at the raw material source and the specifications on that raw material. We use HACCP,

hazard analysis and critical control points, GMPs, employee training, transportation policies and third-party audits. I'll be going into each one of these in a little more detail.

This is where it's going to get a little difficult. We're a little animated here.

First of all, you have to have a preventive mindset. We're very proactive instead of reactive. We believe in continuous improvement. And you truly need commitment from the entire team, from the leadership on down through production employees.

Our raw material specifications. We source 100 percent of our raw material from our own in-house beef packing plant. That's consisting predominantly of about 70 percent culled dairy cows and the rest fed cow. A hundred percent of this material is from animals that have passed veterinary inspection conducted by the USDA FSIS veterinarian.

We also have programs in place where the packing plant employees are trained and are aware of potential risks that they could cause or introduce into the raw materials.

And the last point is we actually have a process where in our specifications where CNS materials, namely brain and spinal cord, are removed at the packing plant and do not enter our system.

If you could put all seven up, just a quick review of the HACCP seven principles. I'll be going into a little more detail on one example at Taylor Packing. But first, in HACCP you assess your hazard. You determine the points at which you can control, potentially control a hazard. You establish limits or critical control points. You then monitor those critical control points. You develop corrective action plans in case something goes astray or gets out of the tolerance that you've set up. You have to keep records on this, obviously. Then you need a verification process where the point is you're verifying the effectiveness of the HACCP program.

The potential hazards in HACCP could be split into three classes--the biological, chemical and physical. When we analyzed our potential hazards, this is what we came up with at Taylor. We have microbiological hazards in a raw material. We have the

potential to have insect infestation in the finished product. There's the TSEs, which are BSE. Chemical hazards such as pesticides, PBCs, dioxins. And then lubricants and oils from our packing plant, which could also inadvertently make it into the product stream. Then also the physical hazards, such as metal and plastic.

This is an example of one of our HACCP programs specifically geared around microbiological controls and the pasteurization step that our cooking process affords. When we first assess the hazard we know that a raw material contains potential pathogens. We determined that our critical control points for these hazards would be the cooker discharge temperature, the raw material grind, the processing rate. And then we established critical limits for these CCPs, basically that for temperature it's a minimum of 270 degree Fahrenheit, for a grind it's a minimum of a 30-millimeter anvil gap on the prebreaker. This is the point at which we grind the raw material. The gap in that equipment cannot go over 30 millimeters. The CCP for rate is a maximum of 36,000 pounds per hour going through the cooker.

The procedures we use to monitor these critical control points. For temperature, it's a continuous monitoring by using a certified thermocouple. The grinding, that actual equipment is inspected several times each shift and then weekly we actually go in and measure the anvil gaps to see how close we're getting to the 30 millimeters. The rate is also tracked by computer.

Corrective action plans. This is if your critical control point control limit gets outside of the acceptable tolerance. For temperature, if we went under 270 degrees Fahrenheit an alarm would go off notifying the operator and what's great about our system is that we actually set it up so the computer would shut off the discharge from the cooker, so it's a corrective action plan that's built into the system.

For grind, if we during visual inspection of that prebreaker see that something is broken, we have to shut down and repair it. Then also I mentioned weekly we are looking at the spacing of the anvil gaps. When it's approaching 30 millimeters we decide to rebuild that.

Rate is simply if the rate starts going over 36,000 pounds an hour we take it back down.

For recordkeeping, both the temperature and rate are tracked on the computer and if there's any alarms that go off, they're also tracked in a separate alarm log. For grind, this is documented by operations and maintenance logs.

Then next, verification. As I mentioned, you're verifying that the process, that the HACCP program is effective. We use, for microbiological risk, clostridium perfingins as an indicator organism. What our approach is is we are getting a kill of clostridium perfingins, we are getting all the other pathogens that could be inherently in our raw material.

We do this testing at 15-day intervals, the idea there being you start out on a Monday, it's two weeks and a day later, you're on Tuesday. We also rotate through each shift as we move through these samples and that way by the end of the year we've had a sample come from every shift of every day, as a verification.

The screen that she's pulling up is the actual real-time screen that the operators are looking at and

you can see down at the bottom there's five different temperatures. The one all the way to the left is our discharge temperature. So this is an example of how the operators can actually watch the temperature profile.

This screen is from our data collection computer that tracks this data. It's actually our physical records. We're not writing these down. It's all computerized with good back-up. You can see there's five lines here. The blue at the top is the discharge temperature. There's a start-up period which you're not discharging and then a shutdown period to the right, but this is the temperature profile in that cooker over the course of the entire day, so we can see from this, looking at the statistics at the bottom, that at no point in time did our discharge temperature go under the control limit of 270.

When we look at GMPs, we view these more as housekeeping issues and general recordkeeping. Our pest control program falls under this. These are issues that deal with facility design or redesign and repair. Our sanitation program fits into a GMP from our standpoint. Then we also have start-up and shutdown procedures.

An example of a GMP would be to prevent Salmonella recontamination of the finished product. We know we're getting a complete kill of Salmonella during the cooking process. It's potential recontamination after the fact.

Our approach is modeled after the animal protein producers industry or APPI approach, which has been adopted by over 99 percent of the rendering industry. Basically we break our facility down into separate processing zones. We have a raw material zone, a cooking zone, a cooling zone for the cracks, storage areas, grinding areas, and protein blending areas.

And the APPI program or these GMPs are built around work habits and policies. One example of that would be that hand tools, things like shovels and brooms, are dedicated to one specific zone. They're not to be carried from a raw material area to a processing area.

We have start-up procedures, reprocessing of product spills. If meat and bonemeal were to somehow come out of an auger and hit the floor you don't just shovel that up and throw it back in the same auger. That

material has to go back and be reprocessing with the raw materials again.

We have dry cleaning of finished product areas. Again you don't want to introduce water for Salmonella growth. And we have many sanitation practices that really go after the targeted hot spots. These are areas where both moisture, time and temperature would exist to grow Salmonella.

We look at facility design and also the equipment maintenance.

The effectiveness of this Salmonella reduction or recontamination prevention program is done by finished product testing for Salmonella on a routine basis.

Now the point here with the GMPs is there's no one critical control point, like in HACCP. There is no one specific kill step for Salmonella that we can put a silver bullet in and say at this point, under these conditions, we will prevent recontamination. However, I'll throw one caveat to that. A few years back the FDA CCM approved the use of formaldehyde as a terminal disinfectant and if we were to use formaldehyde as a feed

additive to disinfect our animal proteins, I would personally consider that a critical control point.

We go into employee training in our approach with modules that are specific to HACCP, GMPs, and standard operating practices. New hires always start their job at an entry trainee position and we actually give them individualized training over several months. To advance in their career development they have to get specific training to the next job they want to move into and we actually--it's kind of like a masters defense-- they have to pass both a written and verbal defense showing that they understand the requirements of that job.

All employees go to quarterly quality training meetings and if we were ever to have a feed safety problem, we would bring the entire team together. The great thing about our facility is it's a very small group, so there's a lot of good communication going on there.

In our transportation policy, our shippers, our trucking companies--everything's shipped by truck--has signed off and certified that they're in compliance. Our

trucks are only to haul agricultural commodities. We ask our suppliers and they have agreed to this, to ensure that their trucks when they arrive at facility are clean, that there's no residual or carry-over from the previous load. Our operators, prior to loading that truck, go through a visual inspection looking for carry-over and there's I don't want to say zero tolerance but we don't want any residue of whatever ingredient was in that truck from a prior load. We don't want it there.

We also look at is the tarp acceptable? Is there any damage to the truck? Basically asking ourselves the question: is the integrity of our product going to be maintained during transportation to the customer? Very important.

Now we manufacture products that are termed prohibited feed ingredients, meaning that they should not be fed back to ruminant animals. And one of the issues that we've had is when we ship this in a truck, as soon as it leaves our facility we kind of lose control. We were concerned about trucks delivering our product to a facility, to a feedmill, say, and then not cleaning out

after that and then going up and picking up soybean meal and hauling it to a feedmill that makes dairy feed.

So we included a provision in our certification for our trucking companies that they would agree to clean the truck after delivering any of our products. We actually put a strip of paper--actually it's florescent orange--on each bill of lading that reminds the driver that they're required by law to clean the truck after delivering this product. It's just one more reminder not required by the FDA--feed raw on BSE--but it's something we thought would be appropriate.

Personally I feel that clean trucks and rail cars are very important, that this inspection prior to loading for any feed ingredient relay should be mandatory. It's just a good practice. There's other potential hazards that could be there. I just think it's a very good common sense approach to look in the truck--is it clean? Is there anything there that could cross-contaminate the product?

We rely heavily on third-party audits, more geared toward the feed role for preventing the amplification of BSE. The first certification that was

conducted a few years ago was through APPI, actually conducted by Cook and Thurber, a prominent third-party auditor, and they found very high compliance within the rendering industry. That was backed up by FDA inspections and then earlier this year that program was discontinued.

So we decided we want to do something, have an additional certification, especially because we have a protein blending plant, so we recently became certified under the Facilities Certification Institute or FCI. The requirements for this program are based upon the FDA rule but have some little extra requirements that you must comply with to be in the program. It requires ingredient supplier and transport certifications from your trucking and rail companies.

In our case, where we commingle beefmeal with other ingredients that can go to ruminant feed in the same facility, we demonstrated the adequacy of our flushing and separation procedures using tracers. And then I should also mention that you have to do this certification on an annual basis, so you can't just do it

and then hold it up for the next five years and say we passed.

So on that I'd like to thank everyone for listening to me today and a special thanks to our folks back in Wyalusing for keeping the place running while I'm gone. Thank you.

[Applause.]

DR. GRABER: Brother Joe is coming up. Joe is with Wenger's Feedmill in Pennsylvania. You notice there's a little bit of a Pennsylvania connection here. John Brightsman runs a good program up in that state.

Anyhow, Joe Garber.

MR. GARBER: Thank you. Good afternoon. I am all that stands between you and the break so treat me well and I will get you out on time.

As a brief introduction to who we are, Wenger's Feedmill, we are a manufacturer of bulk poultry and swine diets. Everything that we manufacture is delivered via bulk loads direct to bulk bins on the farm. We are a family-owned and -operated company founded by Mel Wenger in 1944, headquartered in Rheems, Pennsylvania, which Dr. Graber just mentioned is just north of here. And we're

operating six mills--five in Pennsylvania, one in Maryland. The five in Pennsylvania are actually federally licensed medicated feedmills but we operate all six under the same standards. Corporately we see no reason why anyone would ever want to operate a medicated or a nonmedicated mill under different standards.

We provide nutritional, analytical and research services, in addition to feed manufacturing, and do some pullet growing and egg marketing in case anyone needs any pullets or eggs.

Brief overview. I'm going to take a few minutes to go through our current quality assurance program, kind of a where-we-came-from, a brief moment on HACCP, what it's good for and why we did it, kind of a what-we-just-did, and then the next step, the Wenger system, which is where we're going as a company in terms of looking at quality assurance and food safety.

That's not straight, in case anybody wondered. That was just me in the middle of the night making it crooked.

Our quality assurance programs are customer-driven. We look at everything that we do and we have a

demanding core of customers. And, as you'll see as we go through this, you'll note that a lot of things are obviously for some customers who have some incredible demands.

Our quality assurance program starts at product design and labeling, which is near and dear to me. I started in feed formulation. If we don't have a feed that both contains legal and appropriate ingredients, if we can't create a legal and appropriate label for that feed, really we don't need to go any farther.

So our quality assurance program starts by taking all the ingredient analysis that we receive from our mills, generating our nutrient matrix, and looking at creating diets which are appropriate and will meet the needs of our customers.

The second and actually one of the most important parts of our quality assurance program actually goes into ingredient selection and those three words-- approved supplier list--are an incredibly important part of our quality assurance program and are valuable to a feed manufacturer.

In our company our approved supplier's list is maintained by technical services and formulation, not by purchasing. Purchasing needs to buy ingredients from the vendors that are chosen, that have proven to us that they can deliver safe and consistent ingredients, as are required by the formulas, not as are mandated by what is the most appropriate and most cost-effective for that week.

We place a lot of emphasis on our suppliers--folks like the Taylors and the Princes. As you saw with the two previous presentations, their quality assurance programs are really the foundation on which we need to build ours because that's a crucial part of what we do.

Then production scheduling, which actually begins at our operations with order entry. We relay can't schedule production until we get an order for something to manufacture. Our customers call their orders in. In our order entry software we actually have checks and balances. If you are a producer and you call in and you have laying chickens and you try to order a swine finishing diet the computer will not let it go through. It needs to be a species for which you are on

record as a customer as having. If you try to order any additives, we have the additives coded and obviously we have all medications coded. If someone wants to add a medication at the time of the sales order entry, those medications need to be appropriate for that species. They also need to be within the weights and the clearances that are allowed for that medication for that species. So we do have a lot of checks and balances.

At production scheduling that specific order is assigned a work order number, which the rest of the world would call a lot number. J.D. Edwards calls it a work order number, so that's what we call it. And that number then tracks that load all the way through the system, through manufacturing all the way out to invoicing and any other samples we need to take.

Flushing and sequencing is a very important part of what we do. Being a manufacturer of only poultry and swine diets, we have a little bit of an easier time in terms of BSE regulations. We're not manufacturing any ruminant diets or any of the diets where prohibited proteins are an issue but we do need to be very concerned about flushing and sequencing, especially due to

medications anti-toxic ingredients, if we look at minerals, but primarily our flushing and sequencing is based around customer requirements.

We have a lot of customers who are involved in niche markets. Some don't want animal protein. Some want all vegetable oil. Some don't want bakery by-product. Some want this, some don't want that, and they're just as interested that there's no carry-over of those, in their mind, undesirable, unmarketable ingredients as we are with carry-over, commingling or cross-contamination with medicated feed additives. So a lot of our production scheduling is really based around customer-driven requests and processes.

Involved in manufacturing, which is a large encompassing word which takes everything from our plants where they maintain cleaning books and records. If you don't write down when you swept the floor you didn't sweep the floor and you're going to get in trouble for not sweeping it this shift. So we require records of all our cleaning and housekeeping procedures of our employees. We also maintain records and policies for bin rotation, bin cleaning, making sure that our facilities

have the product move through and we're operating just like the rest of the world, on a first-in, first-out-type basis.

We're keeping medication records. We're keeping batch records. And, of course, all these records--medications, batching--then are also tied back to that work order number, which was generated when the customer called that order in and we have that for complete traceability through the system.

In addition, preventative maintenance. Our maintenance guys don't get enough credit for what they do for our quality assurance procedures. Keeping our equipment running, keeping our scales calibrated, keeping our meters calibrated, just keeping everything functioning to the highest level that they can do it is an important part of everything we do.

Then, of course, we have delivery. Everything is going out in--actually, about 95 percent of our feed we manufacture is going out in a Wenger-owned and employee-driven bulk feed truck in which there's a whole other set of flushing and sequencing. One of our primary concerns then, as we get to delivery, we get into

biosecurity. As Wenger policy, we will not drop-ship feed. It doesn't matter if you get three tons of feed on a 28-ton truck or 28 tons, we're going to bring one truck to you and that truck's going to come back to our facility then. We will not drop-ship or go between different farms because of the density of the livestock that we work with.

And actually, all of our delivery vehicles have an on-board disinfectant unit where we carry about a 25-gallon tank of disinfectant. Underneath each of the undercarriage of all the wheels there are wide band spray nozzles. Going on and off of every one of our customers' properties the drivers are required to activate that spray system and coat the undercarriage with a disinfectant solution to just do everything we can to eliminate any possible vectors for disease.

That's no different than anything anyone else does in the feed manufacturing facility. At Wenger's we're proud to be part of an industry that is proactive. I kind of enjoyed Dr. Sundlof's word stumble where he said break-up sessions. You know, one of the exciting things about a group like this and a meeting like this is

really the feed industry and the center and states and all the groups have done a great job of never breaking up and the fact that we're together and talking about these things is what makes it great.

HACCP. My introduction was what's it good for? Something a few years ago we probably would have had a difficult time answering. From our perspective and what we think HACCP is good for and why we chose to do it is it's really a comprehensive risk analysis focussed with a pinpoint accuracy on potential human food-related illness risk factors.

So what we did is we took our production process all the way from formulation, ingredient purchasing. We invited a cross-functional team at our company. We had sales, financial, human resources, manufacturing, purchasing, technical services, quality assurance. We got everybody together and we spent about 150 hours in a room--not all at the same time--and we went through the entire process and asked ourselves in everything we do is there anything that we're involved in, whether it's an ingredient, whether it's a chemical, biological or physical contamination, that could cause a human food-

related problem? And we looked at HACCP and have taken the corporate philosophy to keep HACCP separate from the rest of our quality assurance programs because our quality assurance really has been primarily based on looking at animal safety, looking at the things that we can do not to get those flocks, those herds, those groups ill and sick because that's an economical obviously advantage for us.

We've taken a look at HACCP and done a lot of things and basically we've created a formal system for identifying risks and tracking these nonconformances, these things that--we at Wenger's define a nonconformance. We made the assumption that our customers expect us to do everything correctly. Correctly means legally and that our quality assurance procedures are covering all the barriers to give them the best product that we can.

So in our definition, a nonconformance is anything that we've done that's going to violate what the customer expects us to do or has asked us to do. And any time that that happens, we expect our employees to fill out a nonconformance report.

One barrier we came to was typically nonconformances are human error. There are occasional mechanical errors but they're often human error. We had a large educational curve to overcome because it's really tough to get people to tattle on themselves. You know, I did this wrong. Okay, please hand that in now. And we had to really work on our employees to make sure that they were aware that the reason we wanted to know those things is because we wanted to look at it from a systems approach. We wanted to look at what we're doing realistically and what we need to change from a systems approach to make sure that we're not putting any human consumers at risk from a product that we may have manufactured or created.

It's been really valuable for us in identifying weak spots in our system. I mentioned the curve of getting folks to "tattle" on themselves when they've created a nonconformance. At 3:00 in the morning when you get the phone call and "The turn head didn't work and we put three tons of this in that bin" and I always have to end the phone call with, "You're going to write the

paperwork, right?" They always say, "Yeah, I'm going to write the paperwork."

Folks have discovered that that paperwork has come to the office, we've started to collect and track those issues and we've made improvements. In a lot of cases we've made a lot of great improvements that have made our mill operators' lives easy and have given them the opportunity to have a voice of things that they saw happening that they thought, well, just no one really cares. Now they have an avenue to report those things to us.

One of the major weak spots that we've identified and have been unable to fix as we've looked at human food safety is the issue of transportation, specifically transportation of raw ingredients to our facilities and even more specifically, looking basically at commodities. In Pennsylvania we need to be constantly vigilant. Demolition waste backhaulers, which is illegal but it still happens and we're aware that that happens. Coal country. We need to be aware that we don't have folks back-hauling coal. Coal is a wonderful thing but it's not real great in a feedmill and we don't want it.

And one of our things that we need to work on as a company and have to really struggle with is how can we get those who are transporting ingredients to us to go to the next level to give us the assurances that the products they're bringing us have not been contaminated either by something that was in the truck beforehand and/or by something being added during transportation.

Last but not least, the quote, "Where are we going?" The Wenger system is a name that was created late one afternoon and we've decided to take a look at all the things we've worked on in the past and create one comprehensive management system, a framework for basically managing all of our not just quality, but all of our environmental and safety aspects in one holistic systems approach.

I hate to get Covey on us but we really need to truly be proactive versus reactive in the things that we do. We've looked to taking these five aspects. Our regulatory, which is our GMPs, which is a lot of what our quality assurance system is based on. Quality, which we're working off the ISO 9000 standard and seeking certification in. And we've found that we really

honestly can't separate quality from environmental, occupational health and safety, and human food safety. We really need to look at these all as one piece.

When we make a mistake in the mill, that's a quality problem. If that feed needs to be disposed of, we've now contributed to the solid waste stream. Now we have an environmental problem. When we have to handle things more than once, we create the potential risk for employees being involved in equipment. That's an occupational health and safety issue.

So we wanted to look at all these together and create one holistic system. I don't want to get all ISO on everybody because ISO's not necessary for everybody but it is what we're looking at. Really it's fairly simple and it's really made sense to us as we've gone forward where we've traditionally been regulatory-driven, we want to do things just to kind of stay out of trouble and then if customers ask us, we do more because we obviously don't want to get in trouble with our customers.

We want to be beyond that. We want to be beyond our customers. We want to say to our customers, "We

already did that." We want to say to the folks who regulate us, "That's fine; we did that already." We want to move forward. We want quality and environmental and occupational health and safety to be a strategic business unit. We want these things to add to our bottom line because we think they're important to our business as we move forward.

As a wrap-up here, these are the reasons that we've looked at implementing a management system which is no different than why we've implemented quality assurance systems but we're trying to take that one step further.

Improved compliance, which should make a significant portion of this crowd happy. Reduction in liability and risk. Our insurers are very interested in that. We live in a world of litigation and we have no desire to be involved in that. A system for prioritizing resources. Like the rest of the world, we live in a world of diminishing margins and resources. We need to be able to put the dollar where it's going to do the most good.

We want to decrease costs. We want to have a market advantage. We want to be able to say to our

customers, "This is the things we're doing." We want to be a step ahead of them and give them the ability to market us to their customers. We want our customers' customers to be proud of who makes their chicken feed. We want them to be able to go to Manhattan, where they sell chicken in a butcher shop, and to be able to throw that butcher in a car and we want them to be able to come and visit a feedmill and enjoy it and appreciate and be aware that the feed that fed the chicken that was processed and is on ice in their facility, they can be proud to sell that, also.

Pressure from interested parties, whether that be regulatory and/or in our case it's mostly economical, from our customers. And obviously continual improvement. If we don't have our eyes on continual improvement, we've really lost focus on what we're doing.

You don't need to see that. That's what we're working on. Everybody knows the continual improvement model--around and around and around.

Just as two last slides, what it's taken to get us this far, looking at creating the Wenger system and integrated ISO system, we required a gap analysis. We

both had a gap analysis from a commercial consultant, in addition to we had a gap analysis done for us by--we actually got a grant from the state and they came in and helped us look at our programs.

We need to have a top management overview. If the individual at the top doesn't believe it, live it, and push for it, you're all wasting your time, I think. We all know that in any organization, that we need to have quality zealots at the top.

We developed a policy. We did aspects and hazards analysis. Just like we did on HACCP with food where we needed to look at every single aspect, we went back and did all that again for occupational health and safety and environmental concerns.

Lots of training with the policy. We developed a manual with all the different levels of documents. We have actually put an RFP out for registrars, convened a steering committee which is kind of our midlevel managers to champion the cause. We just finished on Friday, last Friday, interviewing registrars and we're going to make a decision on that probably Monday. And from this point we're going to complete our documentation, be involved in

aggressive training and education, get a preaudit, and our goal is to have an audit and be certified in ISO 9001:2000, 14,000 and have a letter of compliance for the BSI 18,000 occupational health and safety standard, and have a letter that we're satisfying the seven principles of HACCP by March of 2004.

So that's the schedule of where Wenger Feeds is looking at quality and trying to protect both animal and human food safety and our customers. That's it.

[Applause.]

DR. GRABER: I don't want to put pressure on our next four speakers but you'll have to admit that the speakers so far have been giving us some excellent information about the processes that are occurring at their particular companies.

Okay, as Joe indicated when he started, we're at the break. We've got 20 minutes. Please be back here at 10 minutes of 3.

[Recess.]

DR. GRABER: Okay, we're going to get started. Please sit down.

The next speaker is Mike Merkel. Mike is the director of research and development with Doane Care, Pet Care. Okay, let's go. Mike?

MR. MERKEL: Thank you, George.

Good afternoon. Everybody's all refreshed from break, I can see, and ready to go for the rest of the day.

I appreciate the opportunity to be here today to share an overview of how one pet food company, Doane Pet Care, the firm I work for, manages food safety for dogs and cats. You're probably wondering, well, what does that have to do with animal feed safety? Hopefully there's a lot of things that you'll see that are common in our system that may be beneficial for the programs that you have.

A little bit about Doane Pet Care. We are the largest private label manufacturer of dry dog food, dry cat food and treats in the United States. We sell to over 600 customers, many of whom are in this room and most of the top pet food retailers in the U.S. We have 19 dry extrusion plants, five bakeries that make dog biscuits, and two intermediate moisture pet food treat

plants here in the United States. We also have six plants in Europe.

At Doane Pet Care our mission is to be the trusted partner of choice for our customers' brands. You'll rarely see Doane Pet Care's name on any packages but you will see many recognizable customers' brands and we're entrusted with that responsibility. Consequently, to assure that all of the pet foods that we manufacture and distribute are safe and wholesome for the pets that consume them, we have our means, which is the pet food quality assurance system or PFSS, as we refer to it.

Our pet food safety system is a risk-based preventative system. It begins with a detailed analysis of every pet food processing system at each of our plants and that's important because the system has to be unique for the needs of each of the processing requirements.

This analysis is actually conducted by a team of plant and corporate employees and managers who are knowledgeable of each system and who are trained in HACCP methods. Illustrated is part of a HACCP flow chart from one of our dry extrusion pet food plants. Our typical extrusion process consists of receiving bulk ingredients,

both by rail and by truck, storing those bulk ingredients in bins, taking those ingredients and accurately weighing them out according to the formulas that are issued and controlled by our nutritionist in order to make certain that we meet the specific customer's recipes or formulas.

We then thoroughly mix all of those batched ingredients to assure that we have uniform distribution of all the nutrients for dogs and cats. We then take that batch and we finely grind it into small uniform particle sizes. The reason that's important is we want to have efficient hydration and absorption of water and heat in that mixture during thermal processing.

In the preconditioner we add hot water and other liquids and uniformly disperse that into the mixture. We apply steam, thermal energy and mechanical energy, friction, in the extruder in order to destroy microorganisms under high pressure and temperature in order to inactivate the enzymes so the food is stable and to gelatinize starch to give it the functional aspects of the product.

The cooked extrudate is then formed into desirable shapes and expanded to give us a good texture

that's palatable by the dog and cat. Next, the cooked wet extrudate is exposed to heated air in a dryer in order to remove the excess moisture in order to render the product stable with the water activity. Dried extrudate is then run through a coater where we uniformly apply fat and other palatants in order to deliver the energy and the taste to the product. We then cool that product to ambient temperature so that it's stable for packaging.

You'll notice on this HACCP flow chart that it also includes things like rework, how we handle bulk liquids, and how we handle preprocess ingredients. So it's a comprehensive look at all the potential risks on the ingredients and the processes that we work with.

The next step in our pet food safety system is identifying what the potential pet food safety hazards are and assessing all of the processing and product risks. We identified and implemented critical control points in the process with specific accountabilities and identified corrective measures that have to be taken in the event those things are identified. It's especially important to make certain that all the employees who are

involved in the food safety system are trained in the process control measures.

We require mandatory documentation of all those critical control points in our process, including regular supervisory review and sign-off to assure that they're being consistently maintained. In addition, the documentation is reviewed during corporate and independent pet food safety system audits.

We validate that our prevention system is effective through several means. One, by rigorous testing of our finished products, we carefully monitor our 800 number system, which gives us great feedback from consumers, and regular review by the team of how well the system is working and modifications to keep it contemporary.

It's a well established fact that no one can inspect quality into a product. Consequently, we strive to build food safety into our designs for buildings, which our in-house engineering services group, by the way, builds and constructs most of our plants in order to make sure they're pest-proof, that they're easy to clean, and that they're secure, our grounds so that they are

free from pest harborages and are also secured, and our food processing equipment, which once again we build the majority of, that is safe, easy to clean and sanitary.

We also want to make sure that the packaging that we use is tamper-resistant and that it prevents post-process recontamination of the product. But most importantly, it's the people, making sure they're trained and that they're fully engaged in the pet food safety system.

The eight key components of our pet food safety system are ingredient integrity, a comprehensive quality manual that applies to all of our facilities, sanitation and microbiological control program, integrated pest management, controls of foreign materials, lot traceability, validation of the food safety system's effectiveness by audits, and continuous improvement of the food safety system.

Our quality manual provides uniform policies, standards and procedures for every one of our facilities and also for our distribution facilities. It's ISO 9000-based, even though we're not ISO 9000-certified, and it includes all of the quality system elements that are

applicable to pet food. The quality manual is regularly updated by a standing team of plant and corporate personnel and our quality assurance manual is a controlled and audited document in order to assure that it's uniform and accurately deployed through all the facilities.

Ingredient integrity is where our recipe safety really begins. You've heard from a number of ingredient suppliers and all the comprehensive measures that they go through and that's very important to us. Everybody knows you absolutely have to start with safe ingredients if you want to end up with a safe finished product and no amount of processing or inspection can totally eliminate the adverse effect or impact of poor quality ingredients.

We've found that the most effective way to assure ingredient integrity is to move our quality system upstream. Consequently, we concentrate the majority of our quality assurance time and effort on our vendor assurance program. We certify that our vendors' quality assurance programs are adequate for our needs and the reason for that is that's the critical point at which the

safety of the ingredients can be most effectively controlled.

This is a joint program at DPC between our quality assurance group and our purchasing group and we've actually dedicated a senior ingredient specialist to provide management focus and priority to this critical program. This team of purchasing and quality folks conducts extensive on-site inspections of our vendors' processing plants and their warehouses, as well as auditing their processing and their testing records. All of our ingredient specifications include specific pet food safety requirements that our vendors have contractually agreed to meet.

Now upon receipt, we subject all of our bulk ingredient shipments, like corn, wheat midlings, wheat flour, rice and animal by-product meals, to probe-sampling and analysis prior to acceptance on loading in our plants. We also test all our bulk ingredients with a scanning infrared analyzer and that's mainly done for proximate analysis, not food safety, but one of the interesting unanticipated and novel benefits we've seen is that the scanning NIR that we use also signals whether

or not there's something potentially wrong with the ingredient, the possibility of some mixing with other ingredients that might not show up with the naked eye. This is known as an H value, an elevated H value.

We have a one-strike-and-you're-out policy for high-risk issues like micotoxins. This means that if a supplier has just one load testing out of compliance for micotoxins that they're disqualified. And all of our facilities are equipped for on-site quantification of micotoxins, like aflatoxin and DON, more commonly referred to as vomitoxin. All of our wheat product loads are tested for vomitoxin and all of our corn and rice products are tested for aflatoxin prior to unloading.

Now pictured on the left side of this slide is the quantitative ELISA reader and central data management reporting system that we have in all of our plants. In addition, on the right you'll see that we're picturing our automated fluorometric analyzer, which we have in our corporate laboratory, as well as a number of our larger plants in order to confirm and quantify the micotoxins.

All of our plants are empowered to reject any load that does not meet our specifications and if the

rejection is for high-risk nonconformance like micotoxins, then they would have to go through the entire vendor certification process to requalify.

An often overlooked aspect of ingredient integrity is the transport vehicle itself. Consequently, we've incorporated vehicle inspection as the very first and perhaps most important part in our ingredients-receiving process. Before any truck or rail car can be received onto our sites we carefully check the load documentation to ensure that it's an improved ingredient from an approved vendor processing facility and as amazing as it may seem, we have had loads show up that we didn't order that weren't from approved facilities. So it's very important that we check that documentation.

We also check then to confirm that acceptable flushing procedures were used and documented and also what was transported in the vehicle prior to hauling the ingredients that we received. Obviously that's to prevent cross-contamination. We then conduct a thorough inspection of the vehicle itself for signs of carry-over or other signs of unacceptable conditions.

One simple but very important pre-unloading procedure that we've put in place is pictured in this slide and it's again quite simple. We put a large catch pan under each rail car and truck hopper bottom and a sample's collected and tested. Only if the bottom samples that are collected and the probe samples which are analyzed separately all test okay will the load be accepted in. We've found that this sampling method is a very reliable means of verifying the vehicle's cleanliness and assuring that there hasn't been any ingredient carry-over.

Sanitation and microbiological control is the next key component of our pet food safety system. We employ master cleaning schedules and sanitation standard operating procedures that are specific for each plant and specific for each type of processing equipment. The sanitation and the microbiological control procedures are conducted at the plant level by quality assurance personnel. These procedures include the design and the maintenance of the plants and controlled movement of employees, plant materials, and equipment. It includes predelivery testing and supplier certification of

sensitive ingredients, like palletants, for example, which we apply after our thermal process, and this is necessary, of course, to assure that they're free from pathogens like Salmonella.

In addition, we conduct routine microbiological sampling of plant-specific production sites, environmental areas, and finished products to detect any potential risk. These samples are analyzed in our technical services laboratory, which has extensive microbiological testing capabilities, including pertinent pathogens. The laboratory also provides, most importantly, training at all of our plants for the on-site testing done at the plants and also additional technical support for problem-solving.

Pictured here are two of our microbiology technicians examining and preparing XLD plates for presumptive Salmonella testing.

Integrated pest management is also an important part of our pet food sanitation and food safety program. The two components of our integrated pest management program are first, a master pest control schedule that is specific for each plant, including mechanical exclusion

of pests from all buildings. We rely mostly on nonpesticide-based control measures like insecticutors, pheromone traps and rodent traps, and controlled limited usage of approved pesticides targeted for specific localized infestations that didn't respond to the nonpesticide-based controls.

The second component of our IPM program includes the use of nationally contracted pest control firms and their affiliates for facility personnel training in integrated pest management, automated tracking and reporting of any pest activity at each plant, as well as electronically documenting all plant pest control services and pesticide applications. Any fumigation of ingredient bins or processing areas, if required, is conducted by these licensed contractors.

Foreign material prevention is the next component of our pet food safety system. It begins at the ingredient level at our vendors. We require the vendors to inspect their process, including the transport vehicles and trailers, for foreign material. We include transport vehicles and trailers in our audits at those vendors. We use magnets to detect and remove ferrous

metal during unloading and at key transfer points in the process. We audit and inspect the carriers and warehouses, including packaging materials stored there. We conduct daily in-process inspection at each plant of the physical building and the equipment, including magnets at key transfers and metal detection at packaging.

Pictured is an in-line metal detector typical of our plants, which is coupled with an air-activated rejection diverter in the event any positive sample is detected that can be diverted from the line. This happens to be at one of our dog biscuit bakeries.

Good preventative maintenance procedures are essential to prevent equipment breakdown and deterioration. It's equally imperative to have good standard operating procedures for maintenance repairs or replacements to assure that all the tools and the parts are accounted for and that any work areas are thoroughly cleaned prior to resumption of processing.

As I mentioned, we have an 800 number system that enables us to efficiently evaluate potential consumer concerns and this includes acquiring production

lot information and samples for analysis and plant notification. If we do detect potentially nonconforming materials in our process we have a clearly defined hold system to identify, isolate, document and to prevent the use or distribution of those materials.

Another critical component of our pet food safety system is lot traceability. Needless to say, the ability to trace a potentially contaminated material lot to the finished product code dates manufactured using that ingredient lot and the distribution of those finished products to end customers is very essential.

Our pet food safety system includes the following procedures to establish and maintain a chain of custody for our ingredients and finished products. It starts at the ingredient level where we require and record the lot number on bagged ingredients. This is obviously important for stock rotation, as well. We also have mandatory storage bin designation requirements for the bulk receiving paperwork so we know where every ingredient lot was placed.

We have mandatory origin information, as mentioned, that's required on all bulk receiving

paperwork to validate that materials are only coming from approved processing plants. And we have mandatory batching and ingredient usage records that are critical to link ingredient lots with specific finished product lots.

At the finished product level, all of our packages have legible code dates which designates the plant, the line, the date and time packaged. We conduct hourly checks of those code dates to assure that they're legible and correct.

We also conduct unannounced mock trace and retrieval testing at all of our plants. Now this is conducted and graded by our quality systems manager both for speed and for accuracy. Interestingly, this score counts toward the plant performance objectives. That means it hits the plant manager's bottom line. And we firmly believe that pet food safety performance must be put in the value system of all management and employees at our facilities alike to truly become the way of work life.

The final component of our pet food safety system is comprehensive auditing and continuous

improvement. An annual internal GMP food safety audit is conducted at all the plants. These are performed by trained auditors who were formally quality assurance coordinators at each our plants. Consequently, they're very familiar with the plants' ingredients, processing systems, and procedures.

We also have annual external GMP food safety audits that are conducted at all of our plants and they're performed by nationally recognized independent food safety experts. Both these internal and external scores count towards the plant's performance objectives.

Lastly, many of our customers conduct quality audits and these are performed by trained customer representatives or by industry professionals which our customers have hired on their behalf and ultimately all of these audits ultimately determine business awards.

We also conduct continuing education at all of our plants for the employee population to make certain they're aware of critical issues new and emerging in things like restricted use protein product control procedures, the Public Health Security and Bioterrorism Preparedness Act.

And lastly, the pet food safety system must be flexible, it must be cost-effective, and it must be appropriate for each specific application. It must also take into account technological limitations and resource constraints in order to be practical and self-sustaining.

In conclusion, we do all these things at DPC for the beneficiaries, the dogs and cats. Thank you.

[Applause.]

DR. GRABER: Okay, next on the program is Mike, another Mike, Mike Davidson from California Department of Food and Agriculture.

MR. DAVIDSON: Well, it's a pleasure to be here. I am from California. Arnold says to say hi to everybody and encourages you all to go see "Terminator 3."

Anyway, I'm with the California Department of Food and Agriculture, the Agricultural Commodities and Regulatory Services Branch.

In the fall of 2002 we decided that we could do more to promote feed quality assurance in California so the concept of the safe animal feed education program was brought about. This was presented to our Feed Inspection Advisory Board, which is made up of industry people and a

public member to advise the secretary of agriculture on feed safety activity, feed inspection activities.

It was also presented to the board of directors for the California Grain and Feed Association in early 2003. They liked the idea and so this is what we presented. It was to provide education and outreach materials for feed safety and feed quality assurance training, maintain a web site with feed safety and feed quality assurance information with regulatory requirements and multiple links, and to continue the voluntary feed quality assurance inspections that we've been performing in the last few years.

I guess one of the questions that could be asked is why have a SAFE program? That could be asked by somebody like Richard Sellers, for example. The reason is that we felt the first legislative charge in the California commercial feed law is as follows: enable the feed and feeding industry, with the aid of the state, to ensure every way possible a clean and wholesome supply of meat, milk and eggs for the benefit of the consumer.

There is more livestock feed produced in California than any other state and therefore we must

continue as a leader in the area of feed safety.

Promoting feed quality assurance is the most effective way of preventing unsafe adulteration of commercial feed. As even Dr. Sundlof and many others have indicated, the end product sampling and testing is not going to prevent a problem; you're just going to find it. You don't want livestock to be telling you that you have a problem, or pets.

SAFE is not a new effort. It is the utilization of resources in a more proactive approach to take feed safety and quality assurance programs to the next level.

Okay, basically a three-pronged approach, the first being education and outreach materials. SAFE, in cooperation with the California Grain and Feed Association, will provide feed quality assurance training programs for commercial feed manufacturers. This would be feedmill staff and SAFE and the CGFA will produce a feed quality assurance training manual, including CDs and video cassettes, for firms to provide on-site training.

Imagine a partnership between an industry group and a feed regulatory program. It kind of sounds like a lyric from a John Lennon song.

The SAFE program will provide feed quality assurance training for on-farm feed manufacturers. This first set of trainings are especially designed for personnel on dairies that purchase commodities and mix their own feed. The first quality assurance training for on-farm feed manufacturers is scheduled for next week, September 30. There are two more trainings scheduled for the spring of next year. We hope the SAFE program will be a source of continuous education for purchasers of commercial feed ingredients.

The web site we hope to be a clearinghouse for feed safety information and approved feed ingredients, federal and state regulatory requirements, with example labels posted on the web site. We also have SAFE program updates with a list of available classes, training materials, and research information.

The last component is the voluntary feed quality assurance inspections. They will continue to be performed at feedmills throughout the state. The inspections are not designed to focus only on current good manufacturing practices. These inspections advance

feed safety into all areas of commercial feed manufacturing, not just medicated feeds.

The California commercial feed quality assurance program checklist was developed several years ago by special investigators working in the field. This truly was a grassroots thing that came out of people that were in feedmills every week. It's been revised at least six times, adding items such as a biosecurity section.

AFCO members and industry advisors have worked for a couple of years to develop a checklist for feed safety inspections, also. The AFCO checklist for best management practices guidance document for manufacturing, packaging and distributing animal feeds and feed ingredients--if you get through the name you've got half the inspection done--has 93 inspection items and it is posted on the web site listed on the screen. The California commercial feed quality assurance program checklist has 123 inspection items and it's posted on our web site, as well.

I received a copy of the Canadian Food Inspection Agency commercial feedmill inspection. It's

52 pages. I couldn't find it on the web site but Inspection.gc.ca is their web site address.

Going on with the feed quality assurance checklist, I feel that these checklists are tools for feed safety inspections. They're a feed safety outline from which U.S. FDA regulations could be developed. We feel that this fosters practical, effective and realistic regulations based on actual manufacturing and distribution practices.

State and USDA investigators and industry quality assurance personnel could perform inspections and provide input on the strengths and weaknesses of a proposed U.S. FDA checklist. Next month we plan to have an inspection team use the AFCO checklist, along with the California checklist, to identify strengths and weaknesses of each.

I think that if regulations are developed through a grassroots approach such as this, I think you can have the possibility of a great outcome. This is something that's going to take a lot of thought and effort and will be met with a great deal of opposition.

In conclusion, I hear a lot of industry people stating that every change in the laws or regulations cost money. I had the privilege of attending an AFIA feed safety symposium and I was taught that a truly effective feed quality assurance makes you money in the long run because recalls and complaint adjustments are very expensive. The key is that any new regulations need to be effective, practical and realistic for commercial feed.

Thank you for having me.

[Applause.]

DR. GRABER: Okay, next on the program is Dennis Byrne, also a Pennsylvania connection. You're getting the drift here? Dennis is with the Herr Angus Farms Division of Herr Foods.

MR. BYRNE: Thank you, George. I appreciate you all having me here. For those of you who don't know it, this is extremely scary for an old farm boy. I didn't think I was that old but I'm starting to feel older all the time. I'm left-handed, so obviously I have to come in from a different way than everybody else.

Oh, I thought control-alt-delete just took one slide out. We might have a problem here. Well, it's getting better. I wasn't sleeping much. I mean this really is scary and I didn't know what I was going to do. Fortunately, the good Lord reminded me that this event isn't all that big. He sent me a dear young lady to visit with me Thursday and Friday. Her name is Isabel and I realize that this isn't a big deal, at least not down on the home farm. We've been pretty busy and the nights have been fairly short since then but I was sleeping quite a bit better when I did get to bed. Something about 3:30 this morning just kind of reminded me of Isabel all over again and back up I was.

So I'm glad to be here. I mention of Jim Hogue. You can wave a hand or something. Jim came with me from Pennsylvania. Jim is a nutritionist with Agri Basics. Agri Basics Group does a lot of work with us at the farm. They've been with us for a little over 18 years and I feel real empty without their input, so Jim helped me a lot and I appreciate that. Thank you, Jim.

The other really neat thing is I told my wife since I was picking up Jim, it's kind of on the way for

the carpool this morning. There's five kids that ride together in the carpool so we get to rotate once a week and my wife has Tuesdays. I said, "Well, I can drive the kids for you." So I picked up the kids at the carpool spot and we're going down the road and my daughter Sharon's in ninth grade. She says, "Look, Pops is in a suit and it doesn't have carhard on it." [Laughter.] The kids wanted to know what that was all about, so I didn't tell them too much.

The other thing I really appreciate is Ellis Island. Daddy came over in 1922 as a very small child and somehow or another when Mom was trying to get him and her through immigration they took the O off, so now I get to be at the top of the speaker list. I'm taking this home and bragging about it, all because they took the O off of O'Byrne.

I'll talk a little bit about Herr Angus Farm and we'll move through these, I think, fairly quickly. Herr Angus Farm is a division of Herr Foods. For those of you who are in the Mid-Atlantic region, hopefully you know about Herr's Potato Chips and hopefully you're a steady

customer. If you're not, I grant amnesty and forgiveness; just start buying our product.

Nottingham, if you were to draw a straight line from Philadelphia to Baltimore, which isn't there, sits exactly between the two. We're one mile above the Maryland border.

Jim Herr is the founder. Jim is still alive. He's a great, great friend of mine, mentor, a farm boy at heart. He's 79 today. He's still quite active in a lot of things but the day-to-day plant operations he leaves up to the second and third generation. The company's been around for 57 years, makes all kinds of products. From where I'm at you can't tell anything but all kinds of potato chips, corn chips, pretzels, popcorn, all kinds of salty snacks. About 375 ingredients are either manufactured or resold through the Herr's name.

For those of you that can come visit us sometime, we definitely have the tastiest tour in all of Nottingham, Pennsylvania. I urge you to come, eat some hot chips. Contact me, as well, and I'll give you a little tour of our farm. If you can't do that you can find our virtual tour on the World Wide Web at Herrs.com.

Also, during the holiday season you'll see our tremendous light display that we do every year there and you can take that tour on the web or you can come and do it personally yourselves.

That gives a little background. Herr Angus Farm is very much tied in with Herr Foods. We sit on about 2,000 acres in Chester County. About half of that is woodland and wildlife area. The other half is productive ground. We have the ambition of processing about 1,500 to 1,600 quality Herr Angus beef per year. However, there are cattle that find out what a haven it is to be at Herr Angus, so you'll see some other breeds and colors appear every now and then.

One of the key ingredients to what we do is by-product feeding. We feed potato peelings and also the steer party mix. And quality assurance at any given point of the day will reject popcorn, cheese curls, pretzels for some kind of reason that they think you won't like it so much, so they won't put it in the bag, so they'll send it to the farm. So that's one of the ingredients of our feed.

We also run about 200 head of grass cattle every year. That's usually from about late March till November for us. We work those cattle two ways--the old way and I'm sorry about the Ap but being a Mennonite he was free; I had no choice, Mike. And sometimes we also use the four-wheeler. We also run about 120 brood cows, as well, and our own calves. Again you'll notice that some of the neighbors' cows will just always come over because our grass is greener.

Vision statement, when I thought about this meeting, was in order for a beef farmer to succeed he must provide the consumer with a product that is high quality. That means it better taste good and it better be nutritious, better be fresh. It has to be wholesome, and that's a lot about what we're talking about here. It's got to be safe.

Convenient. Our consumer's a lot different than she used to be or he used to be. One of the great things about the grill is it has helped to increase the demand of beef. You'll see a lot of people buying grills and you won't see very many men say, "Honey, won't you go out and get a chicken for me to cook on the grill." So I

appreciate that. Buy more grills, buy more steaks. I'm a happy man right now. And it's got to be reasonably priced.

In order to continue that enterprise to go on and on, the beef farmer has to provide a product that's going to be that way every time. If you go to a restaurant and you get a bad steak, that's it. You're not going to order steak at that restaurant the next time and that's a bad deal. So we have to think about a consistent high quality eating experience every time.

The second thing is I've got to make money. If I'm not making money producing this great high quality eating experience you have then forget it, I'm not going to be around to produce it for you. And in order to achieve this goal what we've found in the industry is we've got to quick looking at being in the cattle business and we've got to start looking at being in the beef business or in the meat business.

There is a success story and this one started probably 10 or 12 years ago when NCBA did some quality audits and found out there were some problems in the beef on the shelf and the consumer was really getting messed

up because we were using all kinds of names for beef that made it sound like it was high quality and it wasn't. So they started looking at what those quality defects were and began to work backward from the meat case to the producer to conception to improve that.

The purpose of our beef quality assurance can really be summed up in that it's to protect the consumer's confidence in not only the safety of the product but also the quality of the product. What's new is that today the producer is accepting responsibility for that. That did not happen before.

And the other nice thing about this program is that it does have independence from regulatory agencies. It's a proactive event.

Okay, somebody was talking earlier and I forget who it was about quality and staying in business. Two little blips there that happened in the news that all of you will remember. The first one I won't mention Oprah's name but these things cost us a ton of money, a ton of money, and we can't continue to do that. So as things have progressed, producers are recognizing that we need

to do everything we can to build that consumer confidence.

Some of the advancements we've made is we found that the top butt, which is one of the higher dollar cuts, used to have all kinds of lesions in it from injection sites. We've changed that. The injection sites are all done in the neck. Those of you that buy neck meats, I'm sorry, but most people I know like to buy sirloins and top rounds. We've dropped from 22 percent to 3 percent.

The choice and prime product today is hitting the shelves heavier all the time and the dollar spread that I'm getting paid for a choice or prime product is much greater than the select, in the neighborhood of about \$15 a hundredweight right now.

And bruising and some of those difficult things that you got from hauling and trucking cattle to the packing houses caused by horns, we've alleviated that. We're either breeding pulled cattle now or we're dehorning calves young.

Again all about more quality.

Feedstuffs. You know, I've listened to some really good speakers and I recognize we probably still have a long way to go here. As a farmer-feeder, I produce probably--well, my situation might be a little different. About 30 percent of my products are by-products, so they're coming from the factory but all the rest of the product is coming from the farm. We grow our own forages, we grow our own grains, and the only thing I actually buy are some mineral mixes--vitamins-mineral mix and a little bit of protein--soybean meal, sometimes even some urea, so probably less than a pound of that material I'm buying out of a 42-pound-per-head-per-day diet.

One of the things I really have to watch is what herbicides and pesticides am I using on my crops before I make them into animal feed. And I need to know that because there's violative residue issues, as well as just a safety issue. I'm the first customer and so's my family and then you guys are my second customer, so these things concern me.

We want to be sure that all the feeds that we do have coming in are of quality. You know, I probably relax a little bit because I figure that Herr Foods is

buying products that are for human feeds and they're much better standards than animal feeds, so whatever they send me I figure is pretty good.

We have to watch for molds, micotoxins. Most of that's done by sight and smell; secondly, cattle preference. If you're going to give cattle some rotten feed they're not going to eat it. They're going to walk away from the bulk and my objective is to get them to eat as much as I possibly can every day. Forty-two pounds was enough last week, Jim, but next week I want them eating 43 pounds because if they're eating 43 they're gaining just a little bit more and I'm putting more green in the pocket.

BQA talks a lot about suspect feeds and what to do. Again, like I said, I don't buy very many so this isn't an issue for me but in the policy, suspect feeds are to be checked frequently and tested to see whether there's any aflatoxin or molds or something like that that we need to be concerned about.

I had to ask Jim. This one I remember seeing but I couldn't think about it. He straightened me out. We need to justify the feed products that we're using.

Why do I use the Herr party mix? And then verify that it is what I think it is. They're going to send it to the lab, test it, evaluate what's in it. Then I'm going to monitor the results. He might tell me it's a great feed but if the cattle aren't gaining or performing well or not grading the way I want them to, I'm going to say, "Wait a minute. My monitored results say it isn't a great food; what's wrong here?" So that's where we go.

You know, some things are just real common sense. The only postgraduate degree I got was a food handler's permit. I like to eat. Sometimes I like to cook and sometimes I even like to cook for a lot of people and in our county you have to have a food handler's permit in order to serve other people, especially if you get a dollar for it.

So that's something I wanted to do and that took a lot of time and I got awful scared about what food handlers can do. It's kind of a scary business--you know, some of the things that can happen to us. But one thing I learned was that in most cases it's common sense that everybody forgets and that's what this is here. This is just one more example. All of us know that but

you know, when you have a BQA meeting and you mention it, somebody's light bulb finally goes off and says, you know what? I've got my cat food sitting down in the feed room, where I feed my cat, next to my cattle feed. Don't belong there anymore, does it? Or pesticides, fly sprays. You know you're going to spray flies down in the feed room. Well, where are you going to keep your fly spray? Not in the feed room anymore.

So anyhow, it's just a thing. Use some common sense. Make sure we're not putting things around feeds that we shouldn't.

Biosecurity is an issue we're all hearing a whole lot about in all kinds of areas of our life, unfortunately. This is one that we've really been cautious about. Obviously the trouble that England had a few years ago with BSE scared us a lot and then immediately following that they had foot and mouth, which even scared us more because we know how that disease can transfer easily.

One of the things our farm has done for years and years has been open for all kinds of tours for the kids in the local schools, the FFA chapters and that kind

of thing and we kind of shut it down for a while. We like telling the good story that agriculture has and where the food comes from. It doesn't always come from the grocery store; sometimes it has an earlier start than that and we enjoy telling that. But we got pretty nervous when we were reading some of the things that were going on over there and we didn't want it to happen here.

So we watch very carefully where our feet go and also where the trucks come from that bring us cattle or take cattle out. We want to know those kinds of things.

This just talks a little bit about what the BQA policy requires for us when it comes to vaccinating our cattle, doing herd records, and that kind of thing. It's pretty involved and detailed. There's over 900 producers in Pennsylvania that have signed onto this in the beef area and the dairy people are just starting to get pretty excited about it, too, so I expect that number to triple here shortly.

Proper management enhances beef quality and product value. That says it all. I mean that's what we're doing. We're just trying to enhance and get better.

One of the ways we can do that, a lot of people are worried about antibiotics, both injectables and fed. One of the ways we can avoid all of that is to keep animals healthy and that's what this slide talks about. We spend a lot of time thinking about how we can keep these animals healthy. Obviously with only 120 cows you know that I don't raise all of the 1,500 cattle that we market every year. I buy in a lot of cattle, so I've got to talk back and back and back not only from the seedstock grower but also into the backgrounder and then to the people that are providing me the cattle. How are they handled? What vaccines have they had? What medications have they had? What can I do, Jim, when I first get those cattle to make sure that they're eating instead of getting sick? So those are things that we talk about all the time.

Another area that I've seen a lot of improvement in is just total cattle handling and that's something that's been taught a lot to us from BQA. There's a couple of specialists out there that are bovine psychologists. I say that sarcastically but it's unbelievable what they've taught us. If you'd see our

facilities, see a lot of changes have happened. It's very animal-friendly. The cattle move now. We hardly ever have to use a whip or a prod because the way we've changed things, the cattle just naturally want to go forward, so that works out really well for us.

Would you eat what you produce? Doggone right I would and I invite you to come down and have a steak with me any time you're in the area; I'll cook. But it's got to start with that baby calf and it's going to go all the way through while that calf's on its momma to when it's weaned and going through some serious stress to the time it's in the feedlot on a pretty hot ration till it ends up at your shelf. I want you to enjoy that product and I'm going to do everything I can to make it right for you.

BQA is part of a changing philosophy. There's a lot of people wondering why is beef so good right now? I would say that the number one reason isn't the border up above; it's the people in this room. Beef is back because demand is back and people are really enjoying the product today. That's because it's taken us this many years to finally get a product that's a whole lot more

consistent in the grocery shelf, that when Mr. or Mrs. Consumer goes in and buys it, they're confident that when they get it home they're going to enjoy it.

I really believe that and I can back that up with some numbers because we continue week after week after week since the border closed in early June to kill more cattle than we did before. Go figure it out.

Real quick, beef quality assurance. You go through the course, you get trained, you get certified, but it's on-going training. I think Mike talked about that. It's been on-going. We're learning all the time. A few years ago, you know, nobody had to worry about BSE. We didn't worry about meat and bonemeal and where it was but today we really worry about it.

So it's recent and it's every two years and it's a matter of just reevaluating your program on your farm. What could you do a little bit better? All kinds of new information comes out, like I say, regularly.

A technician or veterinarian from the Pennsylvania Department of Agriculture in our case will actually come out and visit your farm and go over your records, go over your feedlots or your cow calf herd or

whatever and just kind of check to see what you're doing and how you might be able to do it better.

Again we're looking at HACCP and I kind of talked about this already. It's putting all the sciences together so that that little baby calf becomes that. It's hard, you know. I live with them things but they do taste good and my objective is to take very, very good care of them every single day that they're alive and recognizing where they're going in the end, but they're going to have a good life when they're with me, anyhow.

That says it all. Only the farmer can really prevent the defect while he's got these cattle. Don't pass the buck onto the next person.

Questions I have raised and Jim has raised concerning this meeting and I don't know if these are questions we're going to break out to or not, George, if they're close to what you had, but I really didn't know what this was all about. Maybe you guys knew before you got here but I'm kind of like, "What is this about?"

But what's considered a threat to human health? I know I know that we're looking at at strategic feed safety program that will result back to human health.

What level of any threatening contaminant can be accepted, if any? How often should ingredients be tested? That's a good question.

If samples are retained, how long should they be held for? You know, it might be one thing in Dave's plant to hold some samples but it would be crazy at my place. Also, which sample? I mean I know you guys may beaucoups of samples but it's probably crazy for you, too. You know, I might make 12 or 14 batches of feed in a day so which one would I save? How would I save it?

And if we are going to sample, who's going to pay for it? That's a big question that farmers would raise really quickly. It costs the same amount to run a sample whether you have 50 cows or whether you've got a 30,000-head feedlot. That's going to be a question that's going to be an issue for a lot of farmers, especially the small feeder-farmer. We're putting a lot of them out of business with regulation, so we want to be careful how we do this.

Feed and food safety are important to all of us, no doubt about it. The current BQA program has been widely accepted by cattlemen and I emphasize widely

accepted. A lot of cattlemen are excited about it and it seems to be meeting at least a lot of our needs for safety and also I think we've seen a big improvement in quality for the consumers. I think we've worked well there.

Recommendation that I would have would be that any mandates that come out of this would fit into that current BQA model, that it would be voluntary.

Well, there you go. There's that Ap again. I'm sorry, Mike. But at the end of a day, and that was pre-Isabel, I'm pretty happy at where I'm at. I really love what I do. I love what I provide. I love the company I work for. My family and I love the food that we get to eat and I feel like God's really made me a very lucky man to be a steward of as much as I am and I'm very thankful for that and I go to bed pretty comfortable, unless I have a meeting like this the next day.

Next slide gives a contact. If anybody wants to talk further or wants to contact me about anything, there it is. I left some manuals at the back. They were BQA manuals from Pennsylvania. I think I see all of them are off that table. They sent them to me and told me to get

them out; if anybody wanted to look through them they could. If anybody would like to see that manual and didn't get a chance to, again contact me and I'll see to it that you get one through our Beef Council Association. Thank you.

[Applause.]

DR. GRABER: Okay, the last speaker before we take a break is Dr. Richard Wood, Food Animal Concerns Trust.

DR. WOOD: Once again I am giving a presentation that our food safety program manager should be giving but he's in another meeting. The last time this happened he was off getting married in Italy. I told him never again but here I am and I'm also a little frightened.

I'm actually coming at this from a completely different perspective than we've been talking about for most of the day because I was asked to step back and take a little at these questions of risk and a comprehensive food safety system from a consumer perspective.

Food Animal Concerns Trust advocates for better farming practices to improve the safety of meat, milk and eggs. As a consumer group we address a range of issues

regulated by the Center for Veterinary Medicine, including a focus on several feed safety issues. FACT has worked over the years diligently with the federal regulatory agencies to develop an appropriate response to bovine spongiform encephalopathy since the mid-'90s and our work on pathogens in feed began when the FDA was discussing a zero tolerance for Salmonella in feed. Recently we've also explored specific feed safety issues that may impact human health.

At FACT we've just completed the Nest Eggs Project, which for 18 years was a for-profit company that contracted with up to 14 egg farms in Pennsylvania, where everybody else is from, except our offices are in Illinois, and we supplied uncaged eggs for major grocery chains stretching from New York to Washington, D.C. and also earlier in the Midwest and our organization itself has about 30,000 supporters nationwide.

During the past 10 years at the regulatory level the primary intervention point for addressing food safety was through processing controls. Many of us here sat around this huge table at the USDA in the mid-'90s to craft a HACCP plan for slaughterhouses and processing

plants. As important as this intervention is, its impact on food-borne disease is mixed. We have seen a decrease in the incidence of campylobacter and listeria but for several other pathogens--Salmonella and E. coli 157 being the most important--we have not seen significant reductions in human disease since 1996. The USDA FSIS has reported recent declines in both these pathogens in its regulatory sampling program. Hopefully in the future we will see these reductions reflected in the incidence of human disease. In any case, slaughter and processing steps need to be combined with preharvest controls if we are to continue this downward trend.

We're delighted that the FDA CVM has recognized the importance of feed in the food chain and is taking steps to develop a comprehensive feed safety system. I've been asked, as I said earlier, to take a step back and identify feed safety risk from a consumer perspective. There are a few of us here in the room, some from groups, and all of us sit down at the dinner table.

This means two things for this presentation, though, in this kind of a setting. First, the obvious.

I am not a renderer, an ingredient manufacturer, a feedmill manager, a state or federal regulator or a producer. Actually, I do live on a farm when I'm not working in Chicago at FACT and FACT has managed egg farms for nearly two decades. But still I'm here today as a consumer. I come representing that part of our lives where we do sit down at the dinner table and want our plates to be filled with food that is safe.

Second, I'm here to identify and discuss priority risks related to animal feed and human health. Therefore I'm going to work through a set of risks that we feel must be responded to in a comprehensive feed safety system. The FDA and/or the industry already have effective controls in place for many of these risks on what I will list and it's been delightful today to hear presentations from various groups that have understood the risks that are out there and are taking concrete steps to respond to those risks with controls.

Still I want to identify those risks because as the feed safety system is constructed, everything must be on the plate. Just because it's working doesn't mean it should be ignored. Other risks I will identify do not

have agricultural controls and will require tougher and more complete controls as far as FACT is concerned and I'll leave most of my comments to those issues.

FACT recognizes that BSE has not been detected in domestic cattle in the United States and that only one infected cow was identified with BSE in Canada. FACT sees this as an indication that steps taken by the FDA and the feed industry have protected American consumers and the livestock industry. Still the occurrence of the mad cow across our border requires us to reexamine our BSE control programs so that consumers can continue to have confidence in what they eat.

The U.S. system and that of Canada are practically identical, as you know. Millions of cattle have crossed back and forth across the border and also all during the period when the cow detected earlier this year was incubating the disease. Any comprehensive feed risk management system needs to acknowledge the possibility that there may be BSE-infected cattle in our national herd. Given this possibility, we need to strengthen our programs aimed at keeping the disease from spreading between cattle.

This first risk is an area where we at FACT, as a consumer group, believe that more needs to be done. Additional steps are under consideration by the FDA. Here are two steps that the FDA should take.

First, the FDA should close the loopholes that exist in the current feed ban. One loophole is the use of poultry litter in cattle feed, as we see it. Both cattle and poultry are raised in large numbers in several regions of the country and it is in those regions where poultry litter is likely to be used as a feed ingredient. It's in areas where they're not raising potato chips or popcorn or whatever the feed ingredient we heard was from the last speaker.

Also, today there may be increased poultry litter recycling due to stronger regulations of livestock waste as an environmental pollutant. FACT does not have explicit data on this practice but in meetings with producers a couple of weeks ago I was told that cattle producers would rather not use poultry litter, even though it is used.

The issue, of course, is that the protein that is passed through the digestive tract of chickens or

spilled from the feeders is a ruminant by-product that can be a protein source for chicken feed. Poultry litter varies in the amount of crude protein from 13 to 31 percent, according to Cross in 1995. There is no evidence to suggest that the digestive tract of chickens will destroy prion proteins, which are not readily destroyed by low pH or digestive enzymes. Also, the practice of composting and drying litter would not destroy the prions if they were present.

So poultry litter can also carry levels of Salmonella and campylobacter, important food-borne pathogens that are also not fully controlled by composting. FACT wants the practice of recycling poultry litter to end.

Another loophole to close is requiring feedmills to establish dedicated equipment for handling prohibited materials unless there is a satisfactory method in place to ensure the effectiveness of steps taken to prevent cross-contamination. Dedicated facilities are the only way to ensure that cross-contamination does not occur, given the inability of the regulatory agencies to provide a daily presence at these facilities, as does the USDA at

their inspected sites. Dedicated equipment is particularly important given the recent history in Europe where cross-contamination is implicated as a likely cause of many of the born-after-the-ban BSE cases. If dedicated equipment is not required, FDA needs to act to prohibit repeat violators of the rule from marketing feed intended for ruminants.

Also, more effort needs to be placed on developing a test for prohibited proteins. If such a test were available, then the effectiveness of procedures to control cross-contamination could be evaluated. Unless mechanisms for testing for prohibited proteins is developed and incorporated into a monitoring system, FACT believes that dedicated facilities are necessary for an effective ban.

Other possible loopholes in the ruminant feed ban that have been discussed more thoroughly in other forums are those of allowing plate waste to be used in ruminant feed and the impact of using automatic meat recovery systems. The USDA just responded a little more stringently to that, apparently. Consideration also needs to be given to the likelihood that some specified

risk materials may need to be removed from the animal food chain altogether, and I think this is a step that Canada may take. An animal feed safety system needs to close the gaps in the BSE feed ban to protect American cattle and human health.

A second step is that the feed ban must be fully enforced. I haven't checked since Hurricane Isabel but the FDA has not updated its compliance information since last year; at least not on its website. Maybe that project is done. But when reviewing the data that is available, renderer and federally regulated feedmill companies looked pretty good a year ago. Last year's GAO report, though, questioned the reliability of FDA's compliance statistics. Statistics aside, it is time for the FDA to move beyond education to enforcement.

An equally serious compliance issue that many of you in this room may want to speak to at some point is the current ability of states to enforce the ban. I understand that AFCD and the feed industry are taking steps to change the state regulatory climate so that the entire BSE rule can be enforced by inspectors in every state. However, most states have serious budget

deficits. It would be helpful to learn how the states are faring in these difficult economic times regarding the ban's enforcement and dealing with compliance and also to learn about the continued federal funding for monitoring BSE. BSE is an area of primary risk for consumers. We feel that further regulatory steps are needed.

The role of pathogens in feed must also be reexamined in terms of their being a threat to human health. FACT has long maintained that if you want to reduce the risk of food-borne illness in humans, you control pathogens in animal feed. This is why for 17 of the 18 years of our Nest Eggs Project in Pennsylvania we cooked the feed for the layers on our farms and then periodically tested the feed for Salmonella.

We all have devoted huge amounts of time and resources to developing and implementing controls for BSE in feed and more needs to be done. Still we have not had any BSE Creutzfeldt-Jakob-related deaths in the U.S. On the other hand, the CDC estimates that bacterial food-borne pathogens account for 5 million illnesses, 46,000 hospitalizations and more than 1,400 deaths each year in

the U.S. While some of these illnesses and deaths are attributed to contamination, some are down the food line beyond the farm gate; animals are the primary reservoirs for these bacteria.

Studies focussing on Salmonella have documented that animals can become infected when eating Salmonella-contaminated feed. Studies presented a couple of weeks ago on E. coli 0157 are still not conclusive at that point, although these studies do see contaminated feed as a contributing factor.

An article published last fall in Clinical Infectious Disease, and I saw copies back there on the table from somebody, by John Crump and others from the Centers for Disease Control identifies three major steps to address animal feed safety out of a concern for food-borne illness. The first step is to establish surveillance of animal feed for microbial contamination, integrating that surveillance with the surveillance of food in humans. This step as I understand it is already under way.

Second is to establish HACCP programs across the animal feed industry to minimize Salmonella. The reports

provided at this meeting from the presenters we've heard in the reports prior to me indicate that this step is already being incorporated into operations on many feedmills and other places.

Third, implement a Salmonella negative standard for animal feed. The FDA announced this policy in 1991. A few years later when I began at FACT I remember the feed industry stating that zero tolerance was impossible and, in essence, what we were asking the feed industry to do was to lie. Today a Salmonella negative standard is a necessary risk management step to protect human health. I know that an industry group has questioned the data from the study that I just mentioned but the validity, to me, of these three steps stands on its own.

In our view, the presence of resistant pathogens or resistant commensal bacteria also needs to be monitored in animal feed. Steps need to be developed to ensure that the highly virulent multi-drug-resistant disease strains, such as Salmonella DT-104 or Salmonella Newport, are not spread through feed.

The undeclared, unintentional or inappropriate use of feed additives is another area of risk for human

health. Drug residues are one such contaminant that can occur due to cross-contamination in feedmills. Medicated feeds left over in the equipment from one batch may contaminate the next batch of feed that is not medicated. Feedmills are required and what we've heard this morning, do implement good manufacturing practices to reduce the risks of this type of contamination. Still, clearly more can be done. One study in Europe in 1998 found that 35 percent of the 250 medicated feeds tested had undeclared antimicrobials and of the 160 unmedicated feeds tested, 44 percent contained antimicrobials.

It's my understanding that we do a good job of controlling residues in the U.S. Still, this risk needs to be on the table as a comprehensive plan is put in place.

An equally important unintentional consequence of a feed additive is when antibiotics are added to the feed to promote growth or to prevent disease. The routine use of antibiotics in this way results in resistant bacteria in the animal. The risk to human health is that if the food product is not thoroughly cooked these resistant bacteria may infect humans,

resulting in antibiotics being less effective in the treatment of food-borne illness.

In 1998 the American Veterinary Medical Association and other veterinary specialty groups, along with the FDA, developed a position on judicious antimicrobial use. This position identifies 10 steps that should be followed in treating sick animals through the therapeutic use of antimicrobials. No such prudent use protocol exists for nontherapeutic uses with animal feed. We believe that a feed safety system needs to address this risk.

Regarding alternative additives, enzymes, antibodies, and so on, we do not know how many of these products will interact with the complex ecology of animal digestive tracts.

Regarding other unintentional, undeclared contaminants, the feed industry has described its control programs for addressing dioxins. Still, the FDA should provide a clear benchmark for dioxin contamination levels. Heavy metals--lead, mercury, and cadmium--are metals of concern. Also, there is a real risk that toxins ingested in livestock feeds can be transmitted

through animal products. The extent of this risk is unclear but these natural toxins are important because of their potential as carcinogens. Everything we've heard today indicates that the industry understands this risk and have controls in place.

As we've heard in the earlier presentations, another way of organizing the human health risks is to determine which source materials are most problematic. For example, downer are already prohibited from being used in ruminant feeds and for good reason. The Harvard BSE risk assessment found that downer cattle are the ones more likely to carry BSE than healthy cattle at slaughter. Downers also carry a higher incidence of food-borne pathogens and illegal drug residues.

The use of reclaimed industrial waste is a risk due to heavy metals, dioxins and PCB contamination. And the use of recycled animal waste is a risk, as discussed earlier, because of BSE residue and pathogen concerns.

In summary, as we take these risk together and place their controls in one system there are several important components to a feed safety system from our perspective. First, the system should establish a mix of

voluntary actions and regulations, as needed. Second, it should require that current feed-related policies be enforced. Third, the riskiest materials should have the greatest regulation.

Fourth, it should provide an integrated surveillance system, beginning with the feed ingredient suppliers and continuing on to human health. The USDA and CDC should also be involved in developing this system.

Fifth, the decision-making process should be transparent. The public must become fully informed of the risks they face and the responses being discussed. And sixth, we must recognize that a comprehensive animal feed safety system does not stop at the feed distributor's door. Thank you.

[Applause.]

DR. GRABER: Okay, the idea for the program this afternoon was really to inform us and to get us thinking about food safety systems and animal feed safety. So really the critical part of the program, as Dr. Sundlof talked, is going to start after the break. That's when

Gloria Dunnavan will explain why you're all here and what you're going to do.

[Whereupon, at 4:15 p.m., the hearing recessed, to resume on Wednesday, September 24, 2003.]

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